HIT Standards Committee
Final Transcript
March 24, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everybody, and welcome to the eleventh meeting of the HIT Standards Committee. A reminder, this is a federal advisory committee. It's being operated in public. There will be an opportunity at the close of the meeting for the public to make comments, and the transcript and summary of the meeting will be on the ONC Web site. Just a reminder to committee members to please identify yourselves when you're speaking so people on the telephone and on the Web can identify you. With that I'll go around the table and ask the members to introduce themselves starting on my right.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Liz Johnson, Tenet Healthcare.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
Anne Castro, BlueCross and BlueShield of South Carolina.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Chris Chute, Mayo Clinic.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Judy Murphy, Aurora Healthcare.

Marc Overhage – Regenstrief – Director
Marc Overhage, Regenstrief Institute and Indiana Health Information Exchange.

John Klimek – NCPDP – VP Industry Information Technology
John Klimek, NCPDP.

Linda Fischetti – VHA – Chief Health Informatics Officer
Linda Fischetti, Department of Veterans Affairs.

John Halamka – Harvard Medical School – Chief Information Officer
John Halamka, Harvard Medical School.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David Blumenthal, ONC.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Wes Rishel, Gartner.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Jamie Ferguson, Kaiser Permanente.

Kevin Hutchinson – Prematics, Inc. – CEO
Kevin Hutchinson, Prematics.

Cita Furlani – NIST – Director of the Information Technology Laboratory

Cita Furlani, NIST.

<u>David McCallie – Cerner Corporation – Vice President of Medical Informatics</u>
David McCallie, Cerner.

<u>Janet Corrigan – National Quality Forum – President & CEO</u>
Janet Corrigan, NQF.

<u>Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services</u>
Karen Trudel, CMS.

<u>Claudia Williams – Markle Foundation – Director for Health Policy</u>
Claudia Williams, Markle Foundation, sitting in for Carol Diamond.

<u>Judy Sparrow – Office of the National Coordinator – Executive Director</u>
Thank you, and welcome to everybody. With that I'll turn it over for opening remarks to Dr. Blumenthal.

<u>David Blumenthal – Department of HHS – National Coordinator for Health IT</u>
Good morning. I must say that this room with its bank of windows is a much more seasonal spring-like light and airy room than the traditional place where we meet. Maybe this is a sign that we are coming out into the open air. That's right. I have to be positive at the beginning of spring. There are leaves on the trees.

Anyway, there's a lot to be positive about. I had the privilege yesterday of sitting in the Department of Interior auditorium to hear the president talk about the bill he had signed and his vision and what drove him forward in pushing that vision. I think it was very revealing that the people on the stage from him, aside from Vice President Biden, were a young man, an 11-year-old boy whose mother had died uninsured, the sister of another uninsured woman who was in the hospital, and a small business owner who was struggling to insure his employees and who would now be getting a very large tax credit to help him do that starting this year within six months and then Vicki Kennedy as the fourth person. For those of us who have been in the vineyards of this project for decades, it was a very moving event, and I think spoke both to the difficulty of getting it through and the promise that it creates, but also the very hard work that remains to implement it and to make sure that its gains for the American people are fully realized.

It has some implications for us, most of them indirect. I think that the assumptions that it is making about our ability to improve the healthcare system, and I'm not talking about CBL assumptions because I think they are very conservative about what our work can accomplish, but I think the assumptions of most people who hope for the best are that the work we're doing will enormously empower many, many aspects of the health system, administrative simplification (a very important part of this agenda), accountable care, quality measurement, the ability to coordinate care through medical homes, the ability to create a primary care workforce, which is enabled in providing high-quality primary care. All these things, I think, are going to be impossible to realize without our success, I think will give even more impetus to what we're doing, create more expectations for us, and move us forward, I hope, with added momentum. Just when you might be getting a little tired at the eleventh meeting of the standards committee, I hope that you will feel invigorated by the way in which we are now front and center for almost everything that the healthcare system needs to accomplish over the next five to ten years.

We have a number of things on the agenda, and John Halamka in Jon Perlin's absence. I don't know how we're going to function with only one John at the helm.

<u>John Halamka – Harvard Medical School – Chief Information Officer</u>
I know John Glaser ….

<u>David Blumenthal – Department of HHS – National Coordinator for Health IT</u>
But if there's any John who can function as a single John, it is John Halamka.

<u>John Halamka – Harvard Medical School – Chief Information Officer</u>
What inspiring remarks this morning. Well, welcome everybody, and it's going to be a very important meeting today because, as you pointed out, there are some very, I think, worthwhile discussion to be had. Doug Fridsma is going to spend the bulk of the meeting talking about NHIN Direct and the NIEM framework as really a back office structure for how we can organize to define requirements and do standards harmonization, make sure that we have implementable artifacts that are testable. We've really tried to structure the agenda to say, sure, there's going to be the usual reports from our workgroups and taskforces, but primarily, we'll focus on Doug's material because I think there'll be a lot of discussion and clarification in that particular area, and we will hear about the certification NPRM.

We'll start today with the implementation workgroup. Now, originally they had a top ten lessons learned in Letterman fashion, and they have reorganized it into three major themes, which I found to be very digestible, so we'll hear from Liz Johnson about that. We'll then hear from Doug, and I think we will see that the timing of our agenda today may be a little bit flexible. Some of the presentations may be a little shorter so that we'll try to give Doug the maximal amount of time today.

Dixie Baker will not be here today. She had a death in the family, so Steve Findlay will present the privacy and security workgroup update. Janet will describe the clinical quality workgroup update. We'll have a brief lunch today, 45 minutes currently scheduled, and then we'll hear from Jamie on the vocabulary taskforce and clinical operations and then finally with Carol Bean and public comment.

Just some quick comments about the recent HIT policy committee meeting that all of the workgroup chairs and I were asked (and Jon Perlin) to present to the HIT policy committee generally what are we working on, what are some of the to-do items, what are gaps, how might we work together to ensure that the HIT policy committee and standards committee are aligned. You'll hear as our workgroup chairs describe their efforts some of the summaries from that included in the slide stacks that were sent out.

These are the slide stacks we used for the HIT policy committee, but it includes such things as clinical operations is working on vocabulary starter sets. Those are very important to make sure that we can get code sets and value sets that are free of charge, downloadable, placed in a central location. We believe that will really accelerate interoperability, and they're working on implementation guidance. You've heard because we discussed this extensively in the last committee meeting the recommendation that broad families of standards be placed in the IFR with a floor of very detailed implementation guidance, so we transmitted that idea to the HIT policy committee, and it was well received.

Clinical quality described that they were focusing on measure retooling and that it's really quite important as we look at 2013 and 2015 to give an early indication of what measures might be part of future years because there's a long lead time to do retooling and testing of quality measures to make sure they're EHR-friendly, that they're implementable, and so Janet said, "Please, speak with us early. Speak with us often, and we will work together closely because we need the lead time."

On privacy and security, some of the major items are how to handle the timing of disclosure. We've talked about that in this committee that there are different timeframes. If you look at the NPRM, meaningful use doesn't require accounting of disclosures until 2015, but yet, there are requirements that if you purchased an EHR in 2009 and before accounting of disclosure really needs to be done immediately, and so we thought that it would be very important that the HIT policy committee and the HIT standards committee privacy and security workgroups align on the timing of accounting for disclosures to make sure that it's very consistent and understandable. The implementation workgroup transmitted the notions that they would be creating an implementation starter kit, and that was also well received.

The outcome of the meeting with the HIT policy committee is certainly there's going to be a lot of interplay between our workgroups. We already have seated a number of HIT standards committee members into the HIT policy committee workgroups, and especially around areas of privacy and security, there's going to need to be a lot of dialogue. With that why don't we turn it over to the Liz Johnson to hear about the summarized major three categories that you folks think will accelerate implementation.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
This is Liz Johnson, and we got the message loud and clear, John, that we should move quickly and give you a very clear synopsis of we've got, so we'll move onto those. That will be our way of approaching this today. I think the way that we went and met with the panels and truly got some very insightful information from what the persons that are trying to use what we're putting out there, what it looks like, what it feels like, and so we have some not only synopsis of what we've learned, but also some … from this standards committee going forward.

I want to give recognition that this is a very diverse group of individuals, and they all worked very hard to make this happen, so thank you to all the members of the committee and the work that you did to make these panels come together and service moderators and so on.

What we really were after in terms of objectives for the hearing was we really wanted descriptions of not only the challenges, but the early wins. There are a number of organizations that have taken meaningful use and are moving down that road very quickly, and we want to be able to gather from those persons their exemplars and roadmaps and guidelines and be able to share those to the private sector as well as taking what's been learned in the public sector. Those were the kinds of persons that we sought to speak on the panels.

We really were looking for implementation advice, and we wanted tangible outputs. You're going to find a number of documents that we were able to obtain, others that are coming in, and so when this process which is now started, as it moves forward in a dynamic manner, we will continue to gather examples and usable items for the public to be able to make sure that they can meet the standards. They will be given actual documents and guidelines and those sorts of things, more than just a written set of standards for them to interpret. Then the one caveat that we were able to achieve was this is really not for solicitation of comments on IFR or NPRM. This is really to bring us information as a whole on the kinds of things they were doing.

We came to four focuses as we went through the day of panels, and they were interoperability, the need for resources and requirements, so let's talk about interoperability. It became very clear as it's been discussed in this panel that they want clear interoperability standards. It is not clear yet how we exchange. Anne Castro's shaking her head at me for those who can't see her. This has become very clear that we don't have this identifiable set of standards related to how we move information from one entity to another, and that is a very clear need going forward.

I think there were other kinds of things that came along, and I think Doug will be talking about some of this today, is that they want source of data to understand how do you tag data, how do you understand what comes in and out of your organization, how do you actually do that, how do you know to trust the data. The comments, and at the back of this presentation you'll see some actual recap of actual comments from the panel, but it was very clear that they want to know what exchange vehicles … and so on.

The second thing was they want resources. They want dissemination of knowledge of tools. The federal panel that Linda Fischetti managed really brought forward some excellent implementation toolkits, and you're going to see in a few minutes that we're going to actually capture and link from the ONC Web site those toolkits so persons are able to go out and actually use that information, bring it into their organizations, and use it as part of the implementation, but we had a number of organizations that came forward. NIST came forward, and I think probably saw they now have their information out there. It is clearly becoming evident that what ONC is doing in other sectors of the federal government have use in the private sector, and we just need to create the synergies and the links so they can get to that information.

Finally, focus on requirements, there was still a clear lack of understanding as to what we want to be done. They want more clarification on meaningful use. We saw an interesting phenomenon, and that is that the providers are clearly focused on stage one and stage one only. Our concern is that, certainly recognizing why they might be there, they're telling us it's because they don't understand what they need to do for stage one, and we worked with them on that, but more so what is coming. Our concern is if they focus on stage one, will they have time to get ready for two and three if they're not already going down that path, so it's very important that we give them the right information to get through stage one, but have that eye on the future so that they are moving and have time to achieve what they will need to for two and three.

Which really leads us to what we want from this committee, and there were four ASPE, three focuses for ASPE, John. The first one was we want greater transparency to the federal resources, and we want this done in a very specific way. Rather than just having links, we would go out and get an implementation toolkit which certainly would be helpful. It would be even more helpful if we could cross-reference and catalog those so if you were looking for an answer to a specific meaningful use, then you could link into that criteria, move into the implementation work kit, and find information on that meaningful use criteria. We want catalog, cross-reference, and easy access. David, we're thinking a librarian would be terrific. He's smiling.

The second thing is we want further clarity and interpretation of the meaningful use requirements, keeping in mind that there needs to be a clear delineation between 2011 with a future eye on what we need to be doing in '13 and '15. There was a suggestion that I think was very good, and that's a frequently asked questions, again, specific to the things that we're hearing over and over and over. Can we delineate a section on the ONC Web site where we have frequently asked questions, the ASPE giving them as much clarity about what's actually required as possible? There's something between simply answering the question in sort of a generic way and giving them an absolute, this is what you must do. We don't necessarily have the expectation that there's only one way to do anything, so there would be more than one way to approach achieving meaningful use, but clear suggestions or options would be included.

The next one is obvious which is provide an understandable or simple set of interoperability standards. That is becoming critical as we go forward and will be needed from this committee.

Finally, sort of the unique suggestion that came out is we would like to see ONC sponsor a forum for EMR vendors and HIE vendors where we could have an exchange of ideas in a less competitive sort of environment. The suggestion originally, one of the software vendors offered to do it, but then you get into a competitive environment where the exchange may be limited, and so what we think is if we could put together forums where vendors come together, exchange ideas and move forward as a single entity in that environment, it would be more positive for our private sector in terms of getting things from the vendor. Every vendor is out there suggesting that they have a way to get to meaningful use, and what we'd like to see is a consolidation so that those who don't have access to that would have the same information without necessarily having to buy the information from a vendor.

In a very simple way, that's kind of what we did in terms of the panels, and then I'm just going to run through the appendix. We're not going to go over it, and then we'll open it up for discussion.

We have already created; it's coming soon as we say. The blog is out there. Now, we're going to add a section for tools. The tools that we began to see come into this environment for the panels, one of the things we asked them was to leave behind documents that could be used and made free to the private sector, and many, many people did that. In fact, all the way to the extent that we have an EMR for the homeless out of Houston, and they're actually going to leave their software behind, so I really believe that there is a true movement that we're beginning to see to share this information.

We are also working on the blog to make it easier to submit comments going forward, so Chris will continue to work on that. Then, John, these are just some of the tools that got left, and I'm not going to read them to you. They're certainly available on the Web site for you, but many of the change management guidelines, all kinds of things that will help with implementation and meaningful use. I'm clicking just through quickly, for those who are on the telephone, just a number of documents. We ended up with a 4 inch binder of leave-behinds that persons were willing to share with us, a very good effort on their part. With that, John, I think we'll open it up for discussion. Please, other members that participated in the panel discussion, it was a very good day, a very energizing day. Those of you who had done panels with Aneesh know that he has many, many questions, so there was much discussion.

John Halamka – Harvard Medical School – Chief Information Officer
Well, thanks very much for that report, and I think you've highlighted a number of themes that we have focused on in this particular committee, so imagine if there was a Web site that said, well, for this particular meaningful use transaction, here are the data elements that need to be exchanged and the vocabularies that need to be used and the detailed implementation guide and samples of the actual standard being used. That would certainly empower everyone. Not only on the technical side, but as you've described, some of this is on more the process and the workflow side, and if there are organizations that have already figured out how their particular organizations, they're doing an assessment of readiness for meaningful use, putting all of that material into that Web site and then offering real transparency to resources.

Just as a side note, I have a number of meaningful use implementers in my organization. I was handed this great t-shirt. I don't know if folks did see these at HIMSS. It says, "My meaningful use is more meaningful than yours."

The first thing that my implementers came up with is they said, well, we're writing all of these various transactions for patient summaries, but we don't know where to get that single list of vocabulary terms that we're supposed to use. Well, I spent the day, and I went over to the NLM for this, and I went over to the FDA for that, and I went over to Reagan Street for this. Wouldn't it be great if there was this resource as you described that your committee produces that makes it easy for everyone. Let us open it up for questions and comments, especially any of those who were at the event. I was going to say, it wouldn't be a standards committee meeting if Wes' card didn't go up, so Wes, you have the floor.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

This is a bit repetitious of what was said at the meeting, but I think that's the idea here. The notion of having a library is more than just putting a bunch of books in a room, and I think it's really important that there be the people time set aside to organize, fill in the odd gap, if necessary, get someone else to fill in the gap so that when someone who is not intimately involved in the process comes to the Web site, they can find their way around.

John Halamka – Harvard Medical School – Chief Information Officer
Basically, what you say which is exactly right is we can't just provide data. We have to provide knowledge. We need a curator, and certainly, the great work at the NLM and trying to assemble a number of resources has been very, very helpful, and there's going to be not only vocabularies and code sets, but mappings and organizing those so people can say, "I can download this and use it in my organization" would be important. Other comments? David McCallie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is a question really for maybe some of the ONC staff. Jodi, over there, maybe you. We had a debate in followup on the testimony about this notion of a frequently asked questions list, and it occurred to me that if ONC hosted such a thing, how do you deal with the question of whether the answers are authoritative from a point of view of, the kind of the questions that we get internally from our clients are would this count? Is this what they meant? Is this the right way to formulate the denominator for this particular measure? If a nurse practitioner placed the order, does that not—these questions that we see over and over again, if they got hosted on an ONC Web site, does that raise issues if the answer comes back of this counts, that doesn't count. Does that become regulatory in some way? Is that a problem? Is it a good thing? Is it a good way to do it?

Jodi Daniel – ONC – Director Office of Policy & Research
That's a great question, and Karen, feel free to jump in on this, too, because you've had a lot of experience with guidance and FAQs. Usually, guidance is not regulatory. It is interpretive, and it does hold some weight. The approach that is usually taken with FAQs is that they're frequently asked questions meaning that we don't usually address specific fact patterns to say, in your particular case, this qualifies, this doesn't. The reason for that is because usually in a question we don't have all the facts we need to actually answer that question.

Usually in an FAQ kind of environment, the answers would be much more general. That being said, if we did come up with guidance of FAQs, they do provide a basis for folks to, it does help people in figuring out whether or not they comply and may make it easier for the entity to make that determination for themselves. Usually, an FAQ would be something that would be more broadly applicable, but usually does provide some help in individual entities thinking through those questions.

John Halamka – Harvard Medical School – Chief Information Officer
Janet Corrigan.

Janet Corrigan – National Quality Forum – President & CEO
A couple of issues on the meaningful use measures, I wonder if people are aware that when the actual quality measures are selected for meaningful use that there will be in the fall very soon very detailed specifications for those. That's really what the retooling is, so there really isn't much discretion, and if people are out trying to figure out how to define the numerator or denominator for what they think might be a measure, maybe we need to communicate better that they don't need to do that. There are folks, the measure stewards, the owners of those measures are working very actively to retool them and develop very detailed and specific that will almost be turnkey specifications for the quality measures. I think we just haven't communicated that to them.

Now, on the utilization measures that are in the NPRM, I'm not aware, and I think this is an issue that needs to be discussed, of any effort to further define those, and I think there's actually quite a ways to go from the brief description that's in the NPRM to something that could be operationalized in a consistent fashion. For those of us in the measure world, we think about those as measures, too, and those are ones that to my knowledge don't have detailed specifications for numerators, denominators, or where you would go in the EHR to find the information from the most reliable source.

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Those are ones that come up.

Janet Corrigan – National Quality Forum – President & CEO
Those are the ones that come up.

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Absolutely, the utilization ones.

Janet Corrigan – National Quality Forum – President & CEO
That's really an issue where I think we need to focus some attention. We don't have detailed specifications for those measures.

John Halamka – Harvard Medical School – Chief Information Officer
Certainly, as you've described, communication is going to be so key. The quality measures by some are called intimidating and there are too many, but yet, they're saying this before they know exactly the detail how numerators and denominators will be completely calculated, and so as you say, these retoolings are going forward. There will be real clarity on the primary care, on the specialty measures, and that would certainly be a very important resource to have linked to this toolkit page, the FAQs. Other comments?

David Blumenthal – Department of HHS – National Coordinator for Health IT
My question has to do with the first recommendation for simple interoperability standards, and that's clearly a major task and mission that the Congress gave ONC and the standards committee, policy committee. Now, we have an interim final rule that contained a whole set of standards and certification criteria. We've heard testimony from the operations working group that has proposed a somewhat different approach after the publication of the IFR than was proposed before the publication of the IFR.

Before the publication of the IFR, the suggestion was for a set of standards, but not for implementation specifications. After the IFR the working group came back and said, well, we're not sure the IFR is the right way to go. What we'd like is families of standards and then detailed specifications.

Now, what I wanted to ask of the implementation group was whether that reflected a change in thinking about, number one, what was required for 2011 because under the 2011 meaningful use NPRM, the requirements for exchange are very minimal, and they're minimal precisely because I think the policy committee didn't think that the standards and the implementation specifications were ready to require more and that we needed time, you all needed time to work on that. I guess the question I would have for the implementation committee is has your thinking changed about what is required for meaningful use in 2011, or is this in effect a recommendation for 2013?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I'll start. This is Liz. We can have others join in. I think you're right, David. I think we clearly understand that for 2011 the requirements are fairly limited; however, sort of like in response to Janet, as we prepare

for the future, we need to start building now for where we need to be, and without specificity, we don't know what to build.

Janet, in response to your, I think we truly understand, and that's what we heard from the panels, that these specifications are coming, but the private sector is building data fields now, and so it's just like they're trying to build for interoperability now. When they don't have clear specifications, they don't know where to go. That's what we hear, not just in the panels, and I know David was alluding to this, but all of us are hearing that in the field—what can I do now to prepare for the future? It feels unclear to them.

John Halamka – Harvard Medical School – Chief Information Officer
Just to amplify that comment, what I hear from the vendor community is all I want is one way to do it. The last thing that you want is a thousand wallflowers blooming that are then going to need to be retooled as we go to 2013 and 2015. Set us on the path so that now we have one floor to begin with that's good enough. We can evolve that one consistent floor.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Can I just ask a followup question? If it turned out that implementation specifications had to be contained in the rules, that is, if the general council were to tell us that we can't direct this field with guidance, I would just point out that the legislation referring to what the Secretary has to adopt talks about standards, implementation specifications, and certification criteria so that if it were to turn out that if you want to recommend to the Secretary implementation specifications, they have to be adopted to rule-making. Would that change what you have suggested in your revised thinking?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I'd have to, David. I hear and understand the replications of what you're saying. I'm just trying to determine based on what we're hearing, what are you thinking, Anne?

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
I'm thinking that it's just going to make our job a little more difficult because we'll have to do a lot of rule changes over time. As the innovation kicks in and the interoperability really starts swinging, we're going to be putting a lot more in there so that people have permission to utilize.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, what we had talked about, and I presume them you can't do that in a rule. What we had talked about was not burying ourselves so tightly inside of a box that we couldn't move around. In the simplest of terms, we're trying to avoid that, and yet, I hear what you're saying. The more specific you get within the rule, then having to change it from a rule change perspective limits our options significantly.

John Halamka – Harvard Medical School – Chief Information Officer
David McCallie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
There are two different levels where there's an interoperability problem, and I think that the detailed fine-grain level around what is the C32 content and what vocabularies should be used, we're making pretty good progress on that. The issues that were raised at the testimony that I heard were at a level above that which is, okay, I have this C32. How do I get it from point A to point B? There's vagaries in the NPRM around is it a downloadable thing from a portal? Is it an email that you can send securely? Does it have to go through a state RHIO? If I put it on a USB stick and give it to the patient, does that count?

It was really about the mechanism whereby interchange occurs rather than what's in the message that was the confusing point. I certainly don't think that should be regulated, by the way, to answer that other question, but I think the clarity needs to come around what are best practice ways to actually interchange the message because we know what the message needs to be. We settled that, I think, reasonably.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
That goes to my point I raised my flag to, and that is that even though 2011 doesn't require a lot of interoperability, the vendors and the providers that are getting their solutions into their entity need exactly the same thing as what you would have for an external communication, so having it now is very important even though it's not required for external entity-to-external entity.

John Halamka – Harvard Medical School – Chief Information Officer
David highlights an important point. When we talk about standards, we talk about content. We talk about vocabulary. We talk about transmission and privacy and security. I think what you're saying is the industry is coalescing on a number of the content and vocabulary standards.

There's work to do, of course, in creating code sets and value sets, but as you've said, there are some implementation guides out there, but on the transport we're going to hear from Doug about NHIN Direct, and there's a whole variety of work that's going on to try to say, do we use REST, do we use SOAP, do we use …. How do we do it? Do we use all the above because right , as we all know, basically the IFR just says REST and SOAP which doesn't provide any specificity. I think one challenge and a question for you, David, is are you suggesting that even if in the regulation we put a floor, then every time we wanted to modify that floor it would have to be done through a regulatory process because that would be frightening.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I'm not sure that I can answer that question, but I think we need to explore what can be done outside of regulation and what can be done inside of regulation. If you are proceeding thoughtfully and with all the best intention thinking that if you can just slip by regulation, if you use this way of phrasing something as opposed to another way of phrasing something that that's going to work, I think we need to give you some feedback about what's possible because I'm not confident given the way the language reads and what we've been told.

The fact is that we were told that we had to adopt standards and certification criteria through regulation, and the law does not treat implementation specifications any differently than standards and certification criteria. If what you're talking about with respect to transport standards is implementation specification or would be classified as that, then I think there is at least a finite probability that we will have to regulate on that as well. Now, if that's what you mean by a floor and you think that floor is going to change over time and it's going to change very rapidly, then I think you need to put into your calculations the possibility that we would need to do that through regulation.

John Halamka – Harvard Medical School – Chief Information Officer
As this committee has recommended, in many areas we would be comfortable with a starting point being put in regulations. It's just we can't let that set in concrete. It can't be ossified. It's going to be very, very much evolving, and as you say, the transport side right now is so changeable it'd be dangerous to put it into regulation. Well, we've had many, many cards go up. Kevin.

Kevin Hutchinson – Prematics, Inc. – CEO
Thank you.

John Halamka – Harvard Medical School – Chief Information Officer
I think Janet was next and then Jamie. Wes, is that still your, okay, so Janet.

Janet Corrigan – National Quality Forum – President & CEO
I think it's a great question, David, and I would encourage you to look at some of the models that have been established over the years to get around this issue of not wanting to put things as detailed as implementation guidance into regulations because it's not nimble enough to be able to respond to the changes. My understanding is that really has been one of the rationales for the development of a variety of private sector standards setting organizations that are recognized under the National Technology Transfer and Advancement Act, and there is a degree of flexibility for the government to work collaboratively with those NTTAA-recognized groups, and it's precisely for this reason.

For example, when you think of the performance measures, at least that's one of the reasons, the performance measures, there is a greater degree of flexibility for the federal government to in its rules identify the measures that the organization I work for, NQF, endorses. We then get into the weeds in terms of the very detailed specifications which can change as frequently as every six months, and you don't have to get all of that into the regulatory process. I believe the same relationship exists with the HIT standards' setting organizations or could. I think it's those kinds of models that you want to look at to keep the detail out of the regulatory process.

Now, those entities that are recognized under NTTAA, we have our own bureaucracy, and it doesn't look that different from rule-making. It's incredibly transparent. There's public comment. There's all that kind of stuff, but it's not as onerous, I think, and it can move in a bit more nimble fashion certainly than the regulatory process. It's a step in the right direction, but it won't make it happen like that, but it is a middle ground, and that's why it's developed.

Speaking of structural standards, that's also the relationship that's been in place for decades between I believe the federal government and groups like the Joint Commission and NCQA to do the more structural assessments. All of the implementation guidance the detail is in those programs which don't end up putting it into the actual legislative process.

John Halamka – Harvard Medical School – Chief Information Officer
Cita.

Cita Furlani – NIST – Director of the Information Technology Laboratory
Actually, Janet caught most of what I wanted to say. If you can specify performance-based standards, that permits the innovation to occur because you're addressing what your needs are, your requirements are, but not how to get that accomplished, so the options are there.

The other point I want to make is that we've had to address some of this ourselves through our federal information processing standards and trying to keep those as narrowly limited as possible in pointing to guidelines. We've published a lot of special publications, guidelines, to augment the more, we aren't quite regulators, but that's as close as we come with the FIPS, and so having to work through that, maintaining flexibility but meeting the law at the same time is something we've struggled with for a long time.

John Halamka – Harvard Medical School – Chief Information Officer
They're good models, NTAA and NIST. With the FIPS activities, one would hope we could just leverage that as we get council and say to already being done through guidance via NIST might we leverage that experience. Jamie.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you, John. This is, again, maybe it's going to sound like I'm just with the chorus here, but at the same time, I want to go back and reflect on the recommendations that we had before the IFR which in fact did recommend both base standards as well as fully detailed implementation specifications for all of the interoperability requirements for 2011 meaningful use. We're coming back and we had a reaction essentially to the IFR saying, well, we're groping towards a different mechanism perhaps of providing that detailed implementation guidance and something that works through the regulatory rule-making process. I think what we're seeing here and what we heard from the implementation workgroup hearing was still a need for that detailed specificity, but not sure exactly the right way to accomplish that.

I just wanted to second, I guess, what Janet and Cita were saying of we would I think want to look for alternative mechanisms, and that's really what we were getting at. The recommendations that we came to in the last standards committee meeting are we're looking for an alternative way to provide that detailed guidance while retaining some degree of flexibility.

John Halamka – Harvard Medical School – Chief Information Officer
Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Across the country around the world, interoperability fails unless there's an economic benefit to both parties … operating. All of the best of intentions, all of the government regulations that are issued, without it, it doesn't happen. We have this opportunity now to create incentives for the healthcare provider side in terms of meaningful use incentives to maybe get something going that can coast as the incentives are less focused. That's a very specific time period to 2015 plus the Medicare penalties that proceed beyond then. That time period's looking shorter and shorter every time I come to a meeting.

I would say that we don't need to relearn the lessons we learned under HIPAA. Now, some things have gone better than others under HIPAA. It's not the big boogeyman where everything failed, but what we did learn is that the model of the omniscient king with lots of time on his hands as a standards maker, CMS in this case, isn't very timely. We know that budgets shift, the attention of Congress shifts. There are all kinds of reasons why that's true.

The other model for standards is the golden rule which is he who has the gold makes the rules, and there I have to wonder how the current PQRI standards came about. Are they in a regulation? If not, is there a model in how they came about for submission to the government which can be used elsewhere? I wonder how in the FAR, Federal Aviation Regulations, are regulations by the name, but they seem to come out much faster than HIPAA regulations. Why is that? What is the mechanism of that happening?

Overall, if we can create the compelling need for both sides to interoperate, then economics favor them doing it in a standard way. Stage one meaningful use requirements that imply interoperability say get it done. They don't say get it done how. We would like to believe that various parties have now jumped on that and say, well, let's see if we can find a common way to get it done how.

Going back to HIPAA, one of the things that works better than others is the establishment of code sets because somehow that does not take the issuing of a regulation to create a new code set. There is an organization designated in the regulation with a reasonably transparent process that announces a new code set, so I really think the two models for doing this are the government has some flexibility to tell its contractors how to do things that is different than issuing a regulation for industry, and if we have the compelling economic motives, that becomes a common platform for people to adopt for economic reasons or specific other models that I know you've been researching heavily inside the government, but it seems that it does happen sometimes.

John Halamka – Harvard Medical School – Chief Information Officer
Karen, any comment on PQRI and how that may be a model for this?

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services
First of all, not all regulations are the same, and some of them do travel on a much faster timeline. One of the reasons that some CMS regulations do is because they contain payment updates, and one of the things that we incorporate in the payment updates is some of our quality measure, so those regulatory processes do happen every year. They're processes that the industry is used to. They're on very tight timelines, and the process is something that is regularized.

We haven't been able to get to that yet with HIPAA, the first round of HIPAA, because it was something that the industry and the government was totally unfamiliar with which was the government setting standards for everyone to use, not just people who dealt with federal agencies was something that had never been considered. The standards organizations were not used to stepping up and really being responsible for getting input from everyone who were now going to be required to use these standards, and we're still years later with 5010 trying to make sure we improve the process.

We keep hearing both from the government side and from the standards community side there's a lot of work we still need to do there, so I think the model to look for is one that is somewhat light touch, but very regularized that people get used to. It's on a standard schedule, and it's expected and understood.

John Halamka – Harvard Medical School – Chief Information Officer
Great, very good. Now, Claudia.

Claudia Williams – Markle Foundation – Director for Health Policy
I'm thinking about some of the recent work that's come out of ONC, whether NHIN Direct or the pop health work under FHA, and in those cases it's been framed as here's a model that will work, not here's the model that you must use. I'm wondering if that distinction suggests alternative paths. If you're simply saying here's something that's worked for others that you might want to adopt. It's not required, whether that requires the same kind of specificity and reg that here's the model would require.

John Halamka – Harvard Medical School – Chief Information Officer
Walter.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I just wanted to emphasize one of the points that have been made, but perhaps push it a little bit farther. I think we have all agreed that through the IFR we have the basis for the what—what are the base standards for different things that we need to achieve or we need to meet. We also have, I think, or will see in the final rule on meaningful use the performance outcomes—what are the things that we need to produce basically and demonstrate and who that we're using this technology in meaningful ways.

But I think, and this is building on the findings from the hearing as well, if there's one thing that people are clamoring perhaps out there is the how. How do I really take all this and do it? Clearly, there is no intent, I don't think, or there should be really an intent of regulating the how in the sense of creating rules that define exactly the mechanisms by which organizations will put all this together, all these standards and all these meaningful use requirements to play, but clearly, there is a need to develop a whole body of resources and literature and examples on different cases.

This is almost taking it personally to the level of examples on different situations on how organizations, a small clinic, a primary clinic in Ada, Minnesota or a larger multi-facility site. Those kind of things that are the basis for organizations now saying, okay, so I know the law says the standard is this, and the law says the meaningful use metric is this, and I now have a series of tools and examples of how I can do the two. Those tools and examples come from various different groups.

I think going back to the HIPAA world a lot of the examples and best practices came actually from the industry itself, groups like … and other groups that helped document, get together organizations and say, how are we going to this A37. Let's talk about the template for helping organization, checklist for helping organizations do this. Those kinds of initiatives and those kinds of resources are the ones that I think we need to focus on in the coming months basically because that's what people will be looking at.

People reading an IFR and people reading a final meaningful use rule are going to be perhaps as baffled as they are today, and they're going to need some assistance in the form of tools and in the form of examples that are not regulated that are just guidelines and ways of showing a pathway for different situations for different organizations and how to achieve it.

John Halamka – Harvard Medical School – Chief Information Officer
Great, well, thank you. Summarizing the discussion, you've suggested that transparency to resources is very important, and so the implementation workgroup can assemble working with ONC on blogs and on Web pages the transparency to resources, clarity of meaningful use requirements, and the use of FAQs as appropriate.

This a discussion that we've had about simple interoperability, it's clear that we need a framework, and that framework is either going to be, once we hear your guidance, something that's in regulation or a floor in regulation, or as Walter just said or as others have said, there may be other models that can be used to issue such guidance outside of regulation. You have had examples like CAQH or … or other groups have said here are implementation guides that are not as you suggested, Claudia, the one way, but a way that works, and you may very well see adoption because you've published such a thing, and it is just by the crown adopted, and it becomes a de facto regulation in a sense.

I think what we'll hear from Doug today is him talking about a framework for doing some work behind the scenes. This actually may help inform us how to have a regular process where we go from requirements definition to clear specifications that are testable and of course working with colleagues at NIST in making sure that these things are actually conformance tested because I think much of the discussion today, although focused on a legal point, is for lack of an ongoing work framework, and that's I think what we'll hear from Doug.

Very good discussion and with that I'd like to move on to the centerpiece of today's meeting, and that is Doug has two presentations for us, one on NHIN Direct and one on a standards harmonization framework. NHIN Direct recently had its first call, and a number of us on this committee are on the early implementation group where we have volunteered to test whatever may come out of this group. Think of NHIN Direct as something that's extraordinarily tightly coupled to the HIT policy and standards committees and to many of us. With that, Doug, tell us more about NHIN Direct.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Can I make a comment or two first, give Doug a chance to open his notebook there. I want to thank Doug. Doug came to work for us a couple of months ago, wandered in from Arizona State. I don't think he realized what he was in for to be at the centerpiece of this swirl of activity around interoperability

standards, NHIN, NHIN Direct, and so on, but he’s done a terrific job, and I just want to thank him for that publicly.

I also want to say that this project, the NHIN Direct, is an effort by ONC to provide the best kind of customer service that we can for the purpose of interoperability, and it’s very much in the spirit of what we’ve been just discussing and that is to think about what a complete toolkit would be for the range of needs that people who want to accomplish interoperability at varying levels consistent with meaningful use over time.

There’s nothing about what Doug is going to be talking about that suggests any departure on our part from the NHIN as it has been discussed here and elsewhere. We continue to fully support that model and see it as extremely useful and essential to achieving the goals of many organizations, that more robust, complete, sophisticated exchange of information, but we have been urged and are thinking through the possibility that other options may also be useful for simpler levels of exchange that are on the pathway toward more complicated exchange and consistent with it and that in fact may be used by organizations that use multiple types and pathways of exchange for different purposes.

There’s nothing about what Doug is going that should change what organizations that are constructively proceeding with building exchange models are doing. We encourage them to keep working at it, at the state level, at the organizational level, but we think we need to make it possible to meet providers where they are, not just where we’d like them to be in terms of their needs and capabilities. If we have only one option for groups that want to be meaningful users and they can't organize themselves sufficiently to get to that option, then we all may have accomplished much less than we hoped we would.

It’s in that spirit of customer service that we’ve tasked Doug with being our spokesperson for this alternative project. It’s not as though we have changed our model or changed our views. It’s simply that we want to be as fully responsive to our broad clientele in the healthcare system as we can be. Doug, take it away.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Thank you, David. I’ve got two presentations. I certainly can give the first presentation and then maybe have questions, but make sure that we have enough time to go onto the second. I just want to make sure that we have time to do that.

I’m going to start every presentation from now until we get it right describing exactly what the NHIN is. The Nationwide Health Information Network is a set of policies, standard, and services that enable the Internet to be used for secure and meaningful exchange. That is going to be a theme that you’re going to hear through both presentations, this notion of policy, standards, and services as defining the way in which we do exchange.

I think to echo what David has already said is that we currently have people that are exchanging healthcare information using the Nationwide Health Information Network in sort of this limited production exchange. The mission that we have within the ONC and the support that we have for this group is continuing and strengthening. We are enrolling more people and having more people that are participating in the current versions of the NHIN, and that work will continue. I want to make it clear that our support for that is strong and that we want people that, again, are going down that path and supporting that, the kinds of activities that we have with NHIN Direct are going to be supportive of this activity as well.

One of the things that happened in the fall is that the HIT policy committee established the NHIN working group and asked us to take a look at recommendations for policy and technical framework for NHIN that would be open to all and foster innovation. Some of the general assumptions of that particular group was that interoperability is not one-size-fits-all and that in fact people will be at different stages of being able to exchange information and that over time we need to foster existing and new exchanges, support increasingly different ways of achieving interoperability, and making sure that throughout this that we maintain privacy and security. While we want to support existing exchanges as sort of a foundation of the future, we want to make sure that we start where people are now and help them get to the kind of exchanges that we anticipate with 2013 and 2015.

Within that framework the HIT policy committee and the NHIN working group came back and gave us essentially four things briefly summarized for us to work on. They said we needed to take a look at secure Internet transport and see if there are both policies and technologies that can support that. Some of that might involve things like addressing an associated directory that allow parties to definitively route information to an intended participant. As part of that, the security framework and the authentication framework needed to be able to authenticate and validate the parties that were involved in that information exchange.

We also felt that they wanted us to look at the trust fabric that provided parties with sufficient confidence that the exchange can be accomplished successfully, and the working group is continuing to look at that trust framework and what are the components as well. We took the advice of that group and very, very quickly began examining what that would look like, and so we started a project called NHIN Direct, and I'm sure people have heard about that at this point.

What I want to do is I have I think 11 slides that build and talk about what we mean by NHIN, the gateway, the connect, the exchange, the project. There are lots of words out there, but I want to make sure that we're all talking about the same thing. I think one of the things that we realize is that the Nationwide Health Information Network is this standards, services, and policies, and being part of the Nationwide Health Information Network is actively using those things to exchange information.

There are sort of four different components that we talk about with this, at least right now. The first is something called the NHIN gateway specification, and there are at least two sets of standards and services that we're working on so far. There's the universal patient discovery which basically allows a doctor to say I have Mr. Jones in my office, and I'd like to know if anybody has some additional information about Mr. Jones that would help me take care of him. People that are participating in exchange can then provide that information to that particular physician.

There's a new set of use cases that we're taking a look at as well, and those are going to be addressed using the NHIN Direct project. Those specifications will address the simple directed communication between known participants of this directed exchange. The NIHN Direct project will actually expand the set of specifications that we have for information exchange.

There's also something called NHIN connect, and NHIN connect is a technology stack that takes the standards and services that are currently within the NHIN gateway specification and creates the software for that. Organizations can actually take the NHIN gateway specifications, and they can either use those services as they're instantiated within the NHIN connect software, or they can create their own, incorporating those. I think of the specifications as the recipe for how to do that interoperability and the NHIN connect software as sort of the resulting cake that would come out of using those recipes.

When we talk about the NHIN limited production exchange, that's a group of organizations that have come together to exchange information, so they've essentially signed this data use and reciprocal service support agreement and have agreed to principles about how exchange would occur. Some of them use the connect software, and some of them are using natively-produced gateway specifications that they've built themselves, but that exchange is a group of people that have come together around the DURSA to exchange information using the specifications and the software that NHIN defines.

The thing that we're going to talk about today, and I know I've kind of gone through all of these things, but I want people to have this available to them so that they can refer to it. It'll be in the packet that you'll get as an update from this meeting. The thing we're going to talk about today is the NHIN Direct project, so it's a project. It has a beginning and an end, and its goal is to take a look and expand those specifications that we have that support that simpler interoperability. It's not a thing. It's a project that's intended to expand our set of specifications. It isn't something separate from the Nationwide Health Information Network. It's isn't something separate from the specifications. It's a project that's going to help us expand the kinds of use cases that we can accomplish there.

At the end of the day, we expect that the same kinds of HIOs and health service providers that may have implemented the current specifications or used the connect software will actually be able to look at this expanded set of specifications and continue to exchange information either using their current way or expanding it using NHIN Direct. We're really just trying to expand the kinds of exchanges that occur, making our specifications more customer-friendly if you will and making sure that all of this fits under the same framework of the Nationwide Health Information Network.

With that as sort of the background, I want to talk a little bit more about the NHIN Direct project and what its focus is. If we take a look at the spectrum of exchange from sort of less complex to more robust, what we're focused on are those simple exchanges that have been defined. Many of the use cases have been defined within the NPRM and in the IFR that has recently come out.

What we want to do is we want to support a broader set of participants and providers so that they can meet meaningful use requirements, understanding that there are multiple pathways to get that, and we want them to fit this common set of specifications. The goal is to look at simple standards' based, widely deployed, and well supported methods for providers to exchange information, and as I've described, this effort is meant to be complimentary and additive to the current NHIN models in the sense that we are going to create some additional specifications that are consistent with what we currently have and will support that broad range of information exchange.

The current project coordinator for that is Aryan Malik, and she is currently doing the job of coordinating all of the various participants that are working on this. Again, we want to identify standard, services, and protocols that support this simple information exchange and ultimately test them in real-world environments so that we don't do these things in the abstract. They are using a very rapid, iterative, model-driven approach with sort of continuous feedback and trying to kind of do this using blogs and wikis and sort of an open development process so that we've got all of those things taken care of in a way that people can participate with the goal that the specifications and standards will be defined in real-world implementations by late 2010. The goal here is quite aggressive, and scope management is probably one of Aryan's principle jobs right now, but we really want to use the ability to sort of take a small piece, develop the services, standards, and protocols, test it, and then gradually expand that as we can.

It's important to recognize that NHIN Direct will not solve the whole puzzle and that it's really focused on this notion of secure routing. These particular items come from Wes Rishel's blog which I thought nicely summarized the kinds of exchanges that can occur and that there a lot of additional services that can be layered on top of secure routing, things like developing a common provider index, developing trust mechanisms, supporting complex multi-party routing, aggregating data for quality or public health, and perhaps other services that we haven't thought about. Those people that are currently using the NHIN connect software or that are concerned that secure routing will somehow make their work unnecessary or not valuable need only look at the other kinds of things that need to be solved within this puzzle and begin taking a look at those things and seeing if we can help them with the secure routing so that they can focus on the aspects that I think are more complex and that will require states and HIEs and integrated health systems to deliver these kinds of services for us as well.

The core use cases within NHIN Direct are the ones that come from the NPRM and from the IFR, and those include things like primary care provider refers a patient to a specialist and include a summary care record, or they refer the patient to a hospital and include those sorts of things. A specialist may send the summary care information back to the referring provider. Hospitals will exchange discharge or continuity of care information, laboratory results. This will include not only intraregional, but also transregional cases where there are secondary or tertiary care facilities.

We've also taken a look at sort of the extended use cases, and many of those involve provider to patients, so making sure that patients can get an electronic copy of their health information, clinical summary records at the end of a visit to provide to a patient, or an electronic clinical summary at the discharge from the hospital. There are also some other things to think about, and that includes thing like quality reporting measures to CMS, quality reporting measures to the states, and medication therapy management in consultation with a primary care provider.

There's a whole series of use cases, and quite frankly, the blog that they've had has had a fair amount of activity. There's actually some posting of some preliminary implementation specifications for review for people to take a look at, and those things have happened within the course of the last couple of weeks. Our kickoff was yesterday.

The NHIN Direct project is using a Web site, NHINDirect.org, for capturing and recording a lot of the information that's being generated. We want this to be open source and open content. We're following the rules of the standards, HIT implementation workgroup, and the principles that have been set up there to make it simple to make sure that we don't let perfect be the enemy of the good, be able to do kind of things iteratively on a consensus basis. We're really trying to take to heart the recommendations of the implementation workgroup in how we formulated this project.

We hope to have drafts, specifications, and services in two months, implementation with working codes sometime over the summer, and deployment by September or October. These are very aggressive timeframes, and that's why I say scope management is going to be challenging task that we have, but I think as you all probably feel there is a sense of urgency in making sure that we get out the 2011 specifications and that we really test whether we can have this kind of community-driven open process. We anticipate three to four face-to-face meetings, weekly teleconferences, and continuous involvement between those folks that are committed to getting to the end stage here. The kickoff meeting yesterday I thought was very, very useful and a lot of good participation that's happening with that.

I've eliminated the actual names of the people that are participating. I'm not sure that we're ready to share all of those things, although I think if you go to the blog, you can figure out who's there, but we have two PHR vendors, seven EHR vendors, five HIE technology companies, six state and regional HIOs, two integrated delivery networks, two consulting firms, one national network for exchange, and four federal partners who are participating in this. We've had very, very good participation, and I think it's important to note that the groups that are participating are not only those that are kind of new to the table, but we have had tremendous support from our federal partners, from the VA, and from the DOD and others who are currently involved in the exchange using the connect software and the current specifications who are committed to making sure that this work is an enhancement of that particular work and that will maintain compatibility across that as well. For that, we are very thankful.

The key project deliverables are going to be some formalized models, and I'll talk a little bit about the interoperability framework. We intend to use the interoperability framework to help us with some of these models. I don't know if we can do all of it with that, but that is our intention is to test that out using this framework. We hope to have core specification service descriptions, some conformance testing scripts and services and really some of the beginnings of reference implementations that are out there as well, so this is an effort for us to really see if we can deliver the kinds of things that our customers need and to engage the customers in a way that they drive the process and we focus on real problems and serve in a role as the coordinating office if you will across these initiatives.

We expect to work very, very closely with the policy committees as well as the office within ONC on policies to make sure that if we identify issues that have a policy implication that we clearly get those things on the table and address those as part of this. At the end we want to have recommendations about whether or not NHIN Direct as a model, both for how we've done this as well as the result of that, makes sense for us as well as to have refinements of this modeling processes and the interoperability framework that we're talking about. We really want to make sure that we've got good communication as part of this process as well. Things are moving very, very quickly, and sometimes it's hard to be able to include the messaging in as timely a fashion as we'd like, and we want to make sure that we can do that. I think one of the reasons for having the blog and these kinds of meetings is so that we can focus on that and maintain good communication with this committee, other committees, and the people that are out there with the boots on the ground.

Here's our timeline that we have. We launched yesterday. We've already got a lot of activity on the blog. We expect to have some second iterations by the end of May, first part of June with development work over the summer and some recommendations by the fall. Obviously, if people want to learn more about that, Aryanmalik@NHINDirect.org. We registered that site within a half an hour, actually, it was during the first meeting that we did that particular, so we've been moving very, very quickly to kind of get the resources and tools together. Obviously, Aryan is going to be one of our key contact people. The NHINDirect.org blog is a place to get lots of information about that, and you can always talk to me about it if you have other questions or concerns. With that I'll stop and then just answer some questions about that, and then we can maybe move on to the next section.

John Halamka – Harvard Medical School – Chief Information Officer
Well, thanks very much, Doug. I think there are a couple of things that David and Doug said that just really need to be highlighted. This is a project. It is customer service oriented. I think, using some words from Claudia, that this is a way, not the only way, and it's an exciting way for people to come together, test new things, try new ideas. Because we were vague in the IFR, there are multiple possibilities, so let's get a group of smart people together to create running code and see what works and what doesn't.

When you think about the limited number of data exchanges that you describe in stage one, there are quality measurement data exchanges. There are e-Prescribing data exchanges, public health lab, … surveillance reporting, immunization reporting, and then various summary exchanges that may go provider to provider or provider to patient. Well, NHIN Direct doesn't do all of those. It isn't an aggregator. There's no master patient or provider index. It is simply a mechanism to solve some use cases for some participants in some circumstances.

I run a health information exchange, and when I heard about NHIN Direct, I thought this is not competitive, and to Wes' blog, it's very complimentary because there are a number of use cases that I as a state HIE don't address. What do you do for the two-doctor practice that just needs to send a referral to another two-doctor practice, and there's no HIE in between? It's a perfect example of how this is just a customer service oriented, let's see how it works. Let's try a lot of experiments, and it's complimentary to all the existing NHIN efforts.

David Blumenthal – Department of HHS – National Coordinator for Health IT

Just to amplify on that, in some ways what would be ideal is if there would be a group in whatever. It could be a regional extension center. It could be a state HIE. It could be a private HIE, and Dr. Y or Hospital X, say it's a 30 bed critical access hospital calls up and says, I want to be a meaningful user. I've got to exchange information. What do I do? The state HIE or the private HIE or the REC says, well, you could be a gold exchanger, a platinum exchanger, a bronze exchanger, and is what each of those means, and we'll send you the toolkit you need for each of those, or you can download them from our Web site. This is exactly what you can do with each of those and what you can't do.

If you want to run a tertiary care level one trauma center where people come in all the time unable to give you their medical history and you need to do all-points requests for their problem list, their drug list, their allergies, you're not going to be happy as a bronze exchanger because all you're going to do is you're going to have to know who the doctor is before you can ask for that patient's information. On the other hand, if you run a family practice of one in a rural area and you only refer to three or four other people and there's only one hospital in your area and you want to be a meaningful user and you can get to meaningful use without having all-point exchange, maybe there's something there for you. That's the option we're exploring, and it may or may not work, but the input we've gotten is that different sizes, different people, flexibility, innovation, keep options open. This is an option to explore.

John Halamka – Harvard Medical School – Chief Information Officer

David.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I'd like to just make a couple of comments. I was, with Wes, one of the instigators of the simple interop notion that kind of germinated into this which I think is an excellent and exciting project. The focus in the early going I think was on the simple aspect of it and the considerations of small offices and something you could do quickly and easily and you could stand up in isolation without the existence required of an HIE and so forth. I think that's all well and good, and it's really important, and it needs to be a driving constraint for what gets done, but I think the more important angle is the direct. What I mean by that is the ability to move information from point A to point B without any side effects, and I think that is something that actually is a core requirement and should be preserved.

I'll make the analogy, and all analogies are flawed, but it's the difference between posting something on my Facebook wall where I intend to broadcast that information and make it available to the people that I've granted access to that wall versus sending someone a private email. The existence of a Facebook wall does not preclude the need for private emails, and I would say that the existence of a robust data aggregation style sharing mechanism does not preclude the need for direct, private exchange of clinical information.

I don't think this is an option that is focused on solving the simplicity problem. I think it is an absolute requirement for the privacy exchange problem. If I don't want a side effect left behind, I need a direct way to securely exchange health information doctor-to-patient, doctor-to-doctor, conceivably patient-to-patient. If we're involved in social networks where people are helping each other manage their own illness and they wish to do that privately, we need a direct route, and it really doesn't have anything to do with simplicity. It has to do with directness and privacy, or so I would hypothesize and open for discussion.

John Halamka – Harvard Medical School – Chief Information Officer
Well said. When I look at some of the things I'm doing in Massachusetts, we have implemented both styles. Sometimes there is NEHEN is not NHIN or NIN or anything. It is a mechanism where larger institutions have created gateways that enable as you sort of describe it sort of Facebook wall kinds of sharing, but some of our EHR vendors have created what I'll call sort of point-to-point capability that is more or less like instant messaging between two docs who are working together, and both models absolutely have their purposes. Janet, did you have a comment?

Janet Corrigan – National Quality Forum – President & CEO
David answered it. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer
Kevin.

Kevin Hutchinson – Prematics, Inc. – CEO
I think the reason I'm having trouble getting my arms around this mentally is because my head was already down a different path as an industry with where we were going with the RHIOs and HIEs, and now I see SHIOs which is state health information organization, the organization versus the HIE technology itself, so I'm trying to get my head around NHIN Direct. I think the question I have to help me position this is twofold. What was the reason for not, you said NHIN Direct is an extension of things going on with NHIN gateway which is where specifications are being built and defined. Why outside of that structure where specifications already in this other area, but we're extending specification requirements now in a different area. It probably is to move faster or do something different than what was being done under the NHIN gateway.

And then, where is this running? Where is this operating, this open source code that's being built? Is it being run in government facilities? Is it intent to run there? Is it specifications that would be run private, state-based HIEs? I'm sorry for the vagueness of the question, but my head was headed down a different strategy path as an industry, and I'm just trying to position this better and where it fits and all that.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Let me try to answer the second question first, and then we'll get back to the first one. Where is this running? We've asked Aryan to deliver us the specifications, the services, the descriptions that we need that will then need to be incorporated into the NHIN specifications, the suite of specifications that we would have. It's not running on a government computer. The project is something that Aryan is managing, and he's convening this group of people and organizing that project to deliver to ONC those deliverables that we talked about, the specification descriptions and some analysis about what works and what doesn't in terms of the reference implementation. This is something that we've charged Aryan to sort of organize, and he is going to be delivering us that kind of work, so it's not running on a government computer per se.

David Blumenthal – Department of HHS – National Coordinator for Health IT
The ONC is contracting for this work. It's being done in, I can't explain, but it's being done in an open source environment. Anyone can get online and then can join, and anyone can follow it. When it's done, it'll be open source. It'll be available to anybody. It might be that no one will use it. It might be that lots of people use it. In that sense it's completely analogous to connect.

It's essentially a government service to the private sector. We're doing the R&D free, and then we're going to throw it out, and it'll be up there ready for use or not. It can be modified. It can be changed. In that sense it's like basic research. Basic research is like open source code. The government does research. It does in the private sector, usually, a university or a think tank, but it's published, and it's available for private industry to use if they want to use it.

John Halamka – Harvard Medical School – Chief Information Officer
It's wikis. It's blogs. It's phone calls and a face-to-face meeting or two, and then a number of organizations as you've outlined have said whatever comes out of this, if it's a java code, dot net code, whatever, we'll test it. We'll let you know. We'll see if it actually fulfills a particular purpose, if it's good or bad. That's really the intent. It's very, very open. There were 40 folks on the call yesterday.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
It's consistent, to go to your first question, it's very consistent with the way in which the implementation specifications for the gateway have been developed, trying to do that in an open and collaborative way. In fact, this is an effort to really sort of leverage what we can do with the Internet to make it even more transparent than what we may have had in the past.

John Halamka – Harvard Medical School – Chief Information Officer
Janet, do you have a followup to that?

Janet Corrigan – National Quality Forum – President & CEO
I find this really exciting because it strikes me as a way to engage a lot of providers in this work very, very quickly and to wet their appetite, and it seems to me once they start using NHIN Direct, they're going to want more capability, and they're going to want to engage in the HIE. They going to want to support it and go further.

If I understand this correctly, though, for this to work in terms of better patient care, you've got to have providers that initiate the exchange. The specialist has to say I'm going to send that summary back to the primary care provider, or the primary care provider has to ping the specialist and say where is the report on the visit. I guess the question in thinking strategically about meaningful use measures for 2013 and 2015, do we really want to, should the policy committee be thinking about, I'm sure they are, but do we as a committee want to think about measures that will encourage and drive providers to NHIN Direct if indeed we believe this is a crucial first step.

Some of those measure obviously would be for a specialist, you could have a structural measure of 80% of your patients you sent a summary of the visit back to the primary care provider. You could have it on both sides for both primary care provider, if you didn't get one within 30 days, did you ping the specialist to get it? You're encouraging it and driving them to NHIN Direct and assuming the next leap then will be that they want more capabilities through the HIE.

John Halamka – Harvard Medical School – Chief Information Officer
A number of cards have come up. I think Marc has been waiting the longest. Go right ahead.

Marc Overhage – Regenstrief – Director
I'll try to be brief, but I'm not sure I'll succeed. First of all, there's obviously a lot of goodness in this trajectory. I'm all for simplicity. Doug talked about his experience in Massachusetts. In Indiana we tried with four sophisticated health organization, very large, to use the NHIN gateway as an approach for

interoperability, and they gave up very quickly. While they're large, sophisticated organizations, it was more energy than they were willing to put into it, so clearly, the simplicity has great potential.

Likewise, I think that an incremental approach as David Blumenthal described is critical if we're going to be successful. If the bar's too high, we're not going to get folks there, and we've always taken the approach of trying to meet people where they are whether it's the physicians in their office where electronically delivering things by fax isn't what you want to do, but if that's the best they could possibly do, you start there and you ramp up.

The couple of things that I struggle with a little bit to see, and this is the Clem McDonald school of informatics where you have to get a string over the canyon if you want to build a bridge. You have to understand how you're going to get all the way from point A to point B or at least to help you figure out where the tough parts to negotiate are going to be and negotiate technically or politically or whatever.

The first couple of things that I think it would be helpful to think through or discuss is we talked about people being able to choose bronze, silver, gold levels, and one of the challenges there is the value that you create through health information exchange. The movement of patient data is partly dependent on network externalities unfortunately, and this is a bad business thing, but it's the realities. If the large trauma center chooses platinum and all the labs in the community choose bronze, the trauma center just lost. You can't have platinum if most of the other providers in the community are bronze. That's a conundrum. I don't know how to resolve that.

The second is that organizations like single solutions. Just a concrete example again, we have in our state for a long time done syndromic surveillance from ADT feeds from hospitals and physicians and others, and the state department of health wanted to add on some additional capabilities and proposed another approach than the existing feeds to do that, and it was revolution. There were protesters in front of the, not quite, but there were urgent meetings held and the state department of health to resign, and providers by and large don't have energy to do things two or three different ways. While the notion say, well, for these things I'll do it directly and for these, it's very difficult for I think a lot of providers, especially smaller providers, and so a single solution has a lot of, so there's another kind of simplicity which is not just the technologic simplicity, but the operational simplicities I think we have to factor in.

The third thing that I think is really important, and this is perhaps the most important, is the trajectory signaling and communications aspect of this. We just finished for the Agency for Healthcare Research and Quality a two-year long deep dive with stratified physician, small practices, large practices, small hospitals. What are your barriers to sharing information for improved care? The number one barrier far and away, tenfold greater than anything else in importance was we don't have time to think about it. That is far and away, it's not the technology. It's not worrying about sharing data. We just don't have time. It's not on our agenda.

One of the things that I think we have to be exquisitely cautious about is when we not change directions because I don't think there's a change in direction, but when we introduce new notions, I think we introduce more uncertainty and lack of clarity for folks, and we see this even in the last weeks people throw up their hands and say, well, I don't know what's going on. Obviously, nobody else knows what's going on. We don't know what the right direction is, so we're going to do nothing because we don't have the bandwidth to think about doing anything. That's a third thing that I think we have to think about.

The last note that I'll make, and John mentioned some of the successes they've had in Massachusetts with NEHEN, and that's obviously a shining example. There is actually a final report coming out any day now from a large five year Agency for Healthcare Research and Quality project where one of the sites was in Utah where they had a well-established administrative exchange, tried to layer on clinical exchange. They already had the doctors and health plans and hospitals authenticated. They already had a secure vehicle for exchanging messages, so they had a lot of the things that might be hard things in putting the string across the canyon, and they failed, and I hope the report will shed some light on where they failed.

Failed is a bad word. They've gone on and done some other things, but it was logistic things. I know one of the examples. I don't know all of them. OBs would try to push to the hospital information about their patient so that when the patient presented to delivery they would have, sounds like a perfect use case for this. They couldn't sort through the mass of stuff that was showing up at the hospital when they actually were trying to take care of a patient in the hospital. It just didn't work, just sort of the human factor kinds of issues. There's some research out there as David said that we've paid for. We've learned from. I think we ought to look carefully at as we go forward.

The last thing is sort of a question or clarification if you will because I heard sort of some distinct things is I heard an implication that NHIN Direct will produce software, and that seems kind of presumptuous at this point in the sense that I thought the idea was a project to explore simple ways to approach this problem and making this up entirely, but there are secure SMTP-based email servers that are out there, well established, lots of healthcare folks use them. Do you have to invent something new? In fact, any time you invent something new it scares me a little bit just because it's so difficult to get there.

Long-winded set of notes, but I think the core question to me is we've got to make sure we can get the string all the way across the canyon and in particular be careful about having the difficult points navigated so that we don't confuse people in the provider world on where they need to be headed and how they get there.

John Halamka – Harvard Medical School – Chief Information Officer
Very, very well said, and from a communication standpoint, I agree with you. Some people say, well, I have so many choices. I just need to, the rest of the community, you decide which is the one choice that's best, and I'll just do nothing. Well, when we heard about NHIN Direct in Massachusetts, we didn't slow anything. We actually are continuing all the stuff we're doing with NEHEN and all the various pilots. This is just yet another tool to explore. I would certainly encourage the communication. As you've said today, it's a project. It is not meant to replace existing efforts. It's complimentary. Doug, did you want to comment on the software issues there, that is, what do you expect as deliverable?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Well, the purpose of the NHIN Direct project is to understand the services standards, and policies to support this simpler directed exchange. I think the corollary to that is that you can't do this in the abstract, and you can't do this just in your head. We could come up with brilliant specifications that simply aren't manageable. They can't be actually implemented or may have tremendous impact on workflow and all those other things that you've mentioned, so there's a difference between producing software because you want to create a production environment and support that than producing software to test a hypothesis that you got the specifications right, and I think we are hopeful that we will get that second rather than the first.

The difference is, is that you're trying to develop something to kind of get out there in the real world, and you're doing it on a tight timeframe. If you notice a problem, you change the software, and if you can, you go back and fix up the specifications. In fact, what we really want to do is we want to make sure that we get the specifications right, and so if we recognize a problem, we have to have that iterative feedback linked to the specifications to make sure that those are correct. The goal is not to produce software, but we need to make sure that we test this in real world so that we get the implementation specifications right.

John Halamka – Harvard Medical School – Chief Information Officer
Thank you. Stan.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
My thoughts, several of them parallel things that Marc has already talked about. In terms of understanding this in the context of other work that's going on, it sounds like an experiment which I'm 100% in support of, and depending on the outcome of the experiment at some point in the future, this might deliberate whether to recommend all or part of that as a standard in some future phase of implementation.

In Utah I think we're not quite as smart as you and Boston I think because it is causing some confusion. If we see these new things we say it's potentially complimentary, but we look at it as Intermountain Healthcare and say we're on the cusp of making an investment to connect through what our state has determined is basically a proprietary solution for a statewide health exchange. That's going to require a bunch of work, and we see a new thing that potentially is going to take some part of that, or we could substitute some part of it and say maybe we ought to wait just a little while, see how this pans out, and then invest our money there rather than invest here and have it be superseded six months or a year from now. There's not an answer to that, but it raises that question. Again, I'm wholly in favor of this experiment. The other things that I'm going to say are just sort of things that I think we need to keep in mind as we go along in this experiment.

In the slides it talked about the development of standards and that it would be an open process. There are open processes, there are open source activities which are open in a different way than open consensus standards processes, and then there's what I would think of as processes that lead to interoperability. The great thing about open source is that you can do things. You can get out there. You've got a lot of people coordinating activities and all working together, but you actually at the end of the day have no guarantee that what you're producing is going to be interoperable. It's a different path and it's a wonderful experiment, but it doesn't guarantee interoperability at the end of the day, and so that's, again, just something to keep in mind as we go along and think at what point or how we introduce back into this not just open source process, but an open consensus process.

It was interesting, in all of the list of participants that you had, I didn't see, and maybe it was hidden under a different label, but I didn't see any of the existing standards organizations represented as part of the participants. They were all basically companies, providers, etc., and so there were no part of the existing open consensus standard process that was represented as participants in this project which was interesting and maybe telling.

This seems to be focused more at sort of the higher level exchange sort of framework and network which, again, is wonderful, and I wonder what level we're shooting at in terms of information exchange. Is it in fact getting the information to somebody to read, or is it getting information again that's at a computable level that allows me to actually incorporate that data's coded, structured, discrete data into my electronic medical record, and if it's the former, that's useful. If it's the latter, that's even more useful, but now that's almost the antithesis of simple because now you're back into all of the what is the real structure of the clinical data. What is all of the terminology? What are the models that underlie that? Even though the exchange mechanism is simple, the content and payload still has all of the sophistication and complexity that, if we want rich secondary use of the data, all of that complexity comes back in and sort of the structure and fine details of the payload that are in these transactions.

The final thing is, especially at the level of this information exchange, I wonder if we're being too focused. What I mean by that is at level this problem is actually not a healthcare problem. It's a problem that's common for anybody who wants to communicate information for a business purpose, and are we adequately in fact taking advantage of whatever is being done as part of semantic network or as a part of electronic commerce where we can just reuse things that are being done for the business industry as opposed to making something new for healthcare when the problem is really the same.

Any kind of exchange of business information requires me to know who I'm sending it to, how to route it, all of those kinds of things. Are we adequately using and reusing the things because at that level of exchange this is I think nearly 100% common with what anybody who's trying to do business on the Internet needs to do, and the part that changes then is that second part that says, what does the payload look like, and how do I make it structured and coded so that I can use and reuse that data for all of the things that are going to actually improve the quality and efficiency of healthcare.

All of that might sound negative, but it's not intended to. Its focus is saying let's do this experiment. As we do this experiment, let's think about these other things because they're going to become issues about how can adopt and integrate this back into the whole framework of what we're doing.

John Halamka – Harvard Medical School – Chief Information Officer
Doug, maybe some comments on the scope of the effort because, as you said, scope … is our biggest enemy in this experiment, and I think that some of the scope definitions will actually allay some of those concerns.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
You're absolutely right. The package matters. We have some specifications for what that package should look like from the IFR. This project is not intended sort of out of scope to really reexamine or to come up with what that package should be. It's clearly something that needs to be looked at, and we need to think about, when we talk about sort of the interoperability framework, we can talk a little bit about some of the approaches that we might do to help integrate across different standards of those kinds of packages.

The focus on this is going to be primarily on transport. There is going to have to be a package that gets exchanged, but that's not the purpose of this project is to focus on that. Again, it's really trying to constrain it to just looking at the secure transport issues.

I think as a result I'm hopeful that the participants that are included will look at other existing solutions and that they will include those sorts of things and take advantage of all of the other things that are going on in the industry. I can go through a lot of what the discussion on the blog has been and what they've talked about, but they clearly are looking at different alternatives and standardized protocols and not trying to come up with a healthcare-specific way of doing this. I think the specificity is going to be in the payload.

John Halamka – Harvard Medical School – Chief Information Officer
For example, in the kickoff meeting yesterday, they actually gave a discrete number of approaches that are all consistent with what other businesses do. Could you use SMTP and TLS like any business would do to route an email? That's a generic issue. Could you use something … with prescribing a certain URI like many folks do today? Yes, there are SOAP approaches that have been used across multiple industries. Are those usable? I don't think there's any reinvention of the wheel.

To the comment about standards, I think you said it very it well. It's not an intent to try to harmonize payload or vocabularies. That's a lot of scope. This is to leverage well-described existing business standards for transport and just test them in various configurations to see if they meet the particular requirements.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
One final thought, it's possible to be good, and it's possible to be fast. I'm not positive it's possible to be really fast and really good. I'm wondering what's driving the timeframe to be so short. Why two months instead of four months?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
2011, we need to be able to do this iteratively. We can't boil the ocean, and we have to figure out how we can take small bite-sized chunks that we can then iterate and improve. We will get to the interoperability framework, and I'm sure that people will have comments there, and the concern there is that this is going to take us three years to get this done.

Why are you doing this? We're trying to move as quickly as we can by scoping things down and trying to provide that incremental approach, but to do it in a framework that allows us to continue each of those iterations builds on the other so that we can have some integration by the time we get to the end. Again, it's a project that we're trying to see if this is a way that we can meet the needs of the people out there and the customers and get their feedback rapidly iterated and help serve in a coordinating capacity around those activities.

John Halamka – Harvard Medical School – Chief Information Officer
Just a quick time check, the privacy and security workgroup update will be rather short. I think the clinical quality workgroup will probably be rather short. I do want to try to get to your interoperability framework discussion because I think there are going to be a lot of questions and discussion there, so if we could just keep the remaining comments brief. Anne.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
I just want to add to the possibility that some states don't understand what we're talking about here. To illustrate that, the amount of discussion here to help us understand how there is or isn't an overlap, how there is a quality better, that's a big question, but in South Carolina, they are floating their first legislation regarding the HIE. Granted it's not done. It'll go through a legislative process, but it is excluding anybody else's ability to perform health-related information exchange without going through the HIE, and I think that goes to a sustainability model that they have to create, and I don't know.

Other states have different things going on, but how does this NHIN possibility complementary. Is it free? Does it conflict with states' intents, and is there communication on this NHIN, not only more for us because there are a lot of people around this table who are actively working with you. I'm not one. How many else are not one, and who all has that wealth of knowledge of what you're really intending because I want to appreciate it, and I want to help my state. I'm just saying South Carolina's like Utah. We just may not understand some of the possibilities or intentions.

John Halamka – Harvard Medical School – Chief Information Officer
Sounds like it's time for a National Coordinator email on the topic.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
That'd be great. I want that. The last thing I want to say is since you're working so hard on simple interoperability and you might get there before us because we don't seem to be able to break our

loggerhead on innovation versus specification, is there a cart and horse situation here, or are there lots of carts and horses in this game? That would be something you could clear up for me. I think he's doing what we're trying to do.

John Halamka – Harvard Medical School – Chief Information Officer
Again, I think that we just tell folks the IFR provided absolutely no implementation guidance. With regard to transport, there are many choices, so there needs to be a laboratory where these choices are tried out, and this is a project to do that.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
So many choices are just going to cost so many different kinds of dollars in a lot of different directions and gold here and platinum here. That causes me a lot of concern if I don't have the same level playing field and I can't count on that being out there. I just need more data. I've concluded I know nothing about NHIN.

John Halamka – Harvard Medical School – Chief Information Officer
Okay, so this is the marching order is the Web page that says the NHIN is not to be feared. We've heard from multiple people about the need for clarity of communication. It is a project. It is a learning laboratory. It does not replace any existing effort, either federal or state, and we will all leverage lessons learned. … At some future date it may be so cool and so wonderful and so cost-effective that we as a body may recommend it. Until then, it is just a project. Claudia.

Claudia Williams – Markle Foundation – Director for Health Policy
You mentioned that as policy issues come up those will be brought for full discussion. I'm just wondering, one, whether any particular issues have come up so far, and two, what the process will be for discussing those. Where will they be brought for discussion, and how will that iterate quickly enough to accommodate your schedule?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
As a pilot certainly we want to make sure that we work very closely because we would like the policy in some sense to get out ahead of some of these issues. I think where it shows up will be coordinated (I think Jodi just left), but with Jodi's office because if it has to do with privacy and security, we have working groups that can help us with that. If it has to do with sort of the existing NHIN exchange, we have an NHIN working group that can help us with that, so there are a variety of mechanisms I think that we can use with that. The point is, is that we want to make sure that there is very, very close coordination and that before anything gets sort of locked in, either from a technology perspective or whatever, we make sure that we have addressed the policy issues and then from there be able to sort of proceed with where the technology might go.

John Halamka – Harvard Medical School – Chief Information Officer
David.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Wes go first because I've already had a shot.

John Halamka – Harvard Medical School – Chief Information Officer
Okay, Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
At great risk to the chain—

John Halamka – Harvard Medical School – Chief Information Officer
We're just going clockwise. That was all.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
If you can be quick, you might want to go first.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I'll go quick, and just another thought experiment, so the first time was a metaphor. This one is a thought experiment to try to make the case around what I think NHIN Direct could address which is imagine if email, the email that we all use every day, had emerged as a secure channel. It isn't today. We know that. It's not a secure channel, but imagine if it had emerged that email was a secure way to send things back and forth. Then we'd all be able to send PHI with email.

I get the question at least once a week from providers using our system asking me is it legal (they say legal), is it legal to send patient information over email. Of course, the answer is, well, it's all this HIPAA rigmarole, but no, it's not a good idea. You should not be sending PHI data over email because email isn't secure, but all of those use cases would be satisfied if we did have a secure way to directly move information from point A to point B. That's no more complicated than email.

In fact, I would argue we could do it with email as long as we make the channel secure, but that's a technical debate. I think that it's a simple problem we're trying to solve. The amazing thing is that the only solution to that problem today is the fax machine which completely destroys interoperability because all you get is a piece of paper at the other end.

We don't need to other complexity to solve the simple problem. We need the other complexity to solve a much more complex problem which is data sharing, not data movement from point A to point B, but sharing from point A to a community. That's a separate problem. It's an important problem, but I would posit that we should solve the simple problem first, simple as in direct, not simple as in it has to be trivial.

John Halamka – Harvard Medical School – Chief Information Officer
What you said is quite correct. The 17 hospitals affiliated with Harvard all force TLS between their SMTP gateways, so if you were sending … from the Brigham to Beth Israel Deaconess, it is completely encrypted between the two locations and Children's and Mass General, etc. It was just a setting in our SMTP gateways which will be one of the things that you test out in your experiment. Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I can't speak for NHINDirect.org. It's a consensus process. It'll do what it does. I can say what I was thinking when I wrote the blogs and as a participant what I try to push for in NHIN Direct. First of all, I have to quote a saint, Saint Christensen that is, Saint Clayton Christensen, one of our newer saints. One of the lessons that comes out of his work is that shooting for the full solution, shooting for the solution that the top 10% of the market needs creates a product that is not suitable for the majority of the market.

We have a tendency to do that in committees because we make a list of requirements. Anything you can do, I can do meta is one of the rules of working in committees, and they get abstract. They get to the point where many of the people participating in the committee are saying, well, I don't know, but if that guys says, then it must be right because he sounds so authoritative. As a result when the output of the committee comes out, it often lags in implementation because of its complexity.

I think Marc said earlier I'm afraid that I might get something running and have it be invalidated by something else in six months. Was that you, Marc, that said that?

Marc Overhage – Regenstrief – Director
I don't think so. Anne.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
It was Anne, okay. It definitely came into my left ear to the right side of my brain. If there's one thing I can promise you, if you have something running, it won't be invalidated in six months. If we've learned anything in our struggle 14 years later to get HL7 up to version 2.3, it's that if you've got something running, it's running.

One of the problems that consensus committees have is they take too long to get a product out. They make it too hard to get started, and after a certain part of time the role of politics and everything else causes a new consensus committee to form, and they have not established that defensive baseline of usage that makes it mandatory for what they're doing to be built upon as opposed to start over. When you change the consensus group, you change the consensus.

Consensus groups are a bit like baby ducks. They tend to imprint on a technology the year they're formed and stay with that technology, so you form another consensus group five years later. They've got a new technology to imprint on.

The lessons that came out of the Internet that went into the implementation group of this committee were get something simple running, let people figure out how to build more on top of that rather than get it all solved and come up with a solution that fits it all. Does that interfere with getting a string before you can build a bridge? Yes, it does. Will it work? Probably it wouldn't if we didn't already have a lot of string, but we have three states represented here that have very different stories on where they are and how fast they're proceeding on health information exchange, four states. I'm sorry. We can never not mention Massachusetts. I would argue that South Carolina is closer to the median than the other three states that are represented here.

We look at meaningful use criteria stage one. Get the certain percentage of your lab results in structured format. Implicit if you look at the complete opus, everything that ONC has produced, you might read that to say get that done through the HIE, but if you did, then you could write off 2011 in most states. 2013, frankly, if you're really depending on the HIE, we will have had a mixed bag of results, like every other program that goes out to the states there will be some fantastic success and innovation and some things that take longer than others.

In the meanwhile the economics of our business are changing. We have a consolidation of EHR going on. They are more likely to be remotely hosted than they used to be. They are frequently offering as a value-added service importing lab results into their systems. We have the very largest technology vendors all of a sudden interested in us because there's some money in healthcare now, so it is clear that this start simple, get a simple activity which is delivering a payload which can be standard, get that working broadly, creates a lot of new experiments in how to restructure.

To that extent there may be SHIEs, I'm just glad we didn't come up with a State Healthcare Information Technology acronym. I'll bet you somebody wrote it, and then it got edited out somewhere along the line. There may be those that say we did this RSA. We were told we had to franchise on exchanging data in our state. It wouldn't happen unless we did it. Therefore, we can take our time and do it right. Well, maybe it won't be so bad if they feel that they don't have the franchise. They have the opportunity. All in all, I am sorry that what I started has created this confusion, but I'm not sorry.

John Halamka – Harvard Medical School – Chief Information Officer
Thirty seconds.

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Wes, too, and I have talked about this a lot that it's not the technology that's slowing this down. It's the will, the alignment of incentives, and the energy. I'm not at all convinced that a simple technology solution is going to help us.

John Halamka – Harvard Medical School – Chief Information Officer
It all depends on the proposition that the incentives for meaningful use are an incentive. If you accept that, then the rest follows. If you don't, then it doesn't. Last word on this one, Walter, and then we will move on to the framework.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I'll try to make it just one word. First of all, I wanted to thank you for the presentation. I think pushing hard to show more clarity about what NHIN is, is wonderful, and I think classifying and categorizing things in the way you've done it is great.

To start, I just wanted to say when I was at HIMSS, I went through the 17,000 displays and went to actually the interoperability showcase, and a lot of people were showing how they can connect direct now, and they can do NHIN Direct, and they can plug-and-play with NHIN. It was interesting because it was a novel and very good concept of saying, all right, so NHIN is there. We're going to have HIEs. HIEs internally are going to connect their groups inside, say a state like Minnesota connects all its groups. Then between HIE there's NHIN to connect HIE to HIE, but then there's going to be pockets of people or organizations that can't go to an HIE or that choose not to go to an HIE or that are going to be organizations that are large enough to be directly connecting to NHIN, so there is an indirect option.

That was and I think is still a very good concept. I have downgraded that now based on all the discussion, this being now seen as a project with a start and an end because I always thought it would be great to have that as a real valid option out there that NHIN Direct exists to allow organizations that don't have access to an HIE to be able to connect to NHIN. Otherwise, what's the doctor in Ada, Minnesota again going to do if they can't connect to the state HIE in Minnesota because they couldn't reach that, or how their other organizations are going to do. I think I wanted to plug the concept that there should be an NHIN Direct, and there should be a delivery way or a mechanism for organizations to connect directly whether they're large or small.

The second concept I wanted to mention is that there is a distinction between packaging and sending and access to information, the process of accessing. Basically, NHIN Direct as I understand it now is a way to package and send, to send out from my organization to someone else. It is in that respect is a very good, going back to the earlier discussion on the implementation workgroup, the concept that I mentioned about there's a what and then there are the outcomes, and what we need is a how, an example of a how. This is a perfect demonstration of different hows on how to package a message and send it out.

But there is a need to conceptually understand the whole process of access which is very different. I'm not sending my packet to someone else, and I only need to secure a channel and encrypt and digitally sign and have some nonrepudiation to make sure that they received the right one and all those things because I'm sending it out. When dealing with access and dealing in an environment that organizations are going to come to access my data and knock on my door, or I'm going to have to go and knock on the door of someone else's organization and try to access the data. I think there's a different concept, so clarifying that I think will be very valuable. If the real, true scope is exclusively on packaging and sending, that's one thing. If the concept is a much more encompassing true NHIN Direct option that allows people to do that send as well as to do the access process, I think that would be valuable.

With respect to that, I think HITSP back in the HITSP days had created a package of elements that infrastructure security and privacy elements that any type of accesses should consider having, including of course secure communication, including audit logs, including authorization of …, and the dreaded access control capability. There is a package of things that regardless of which exchange you're doing you must always do those elements in your access capability, then some of those building to the send instead of just access. I think there needs to be also some clarity about the package of security and infrastructure elements that are going to be part of this.

The very last comment I think is all about managing expectations and helping people understand what this is because out there, again, I think the concept, the feeling, the sense is that NHIN Direct is truly an alternative to if I can't access NHIN via HIEs, then I have NHIN Direct. It will be helpful to … and, again, my last thought is to truly make this not just a start and end project, but a true NHIN option for organizations that can't access NHIN via an HIE.

John Halamka – Harvard Medical School – Chief Information Officer
Great, well, thanks for those comments. I think the committee has had a rich discussion about what NHIN Direct is and what it isn't, and I would hope that every time we get together in the next several months (because this is moving fast) that we get updates as to what we've learned. Walter, to your point, it may very well evolve into an option … investigation. Doug, take us through the interoperability framework. If there's anything that I've learned in running an interoperability framework through HITSP for the last five years, it's really important to have a process to define your requirements. It's really important to produce detailed implementation guides, and it's really important to have something that's testable for conformance. What I hope we'll all hear is Doug's thinking on a framework to help us with those kinds of things.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Great, so now on to something that's more controversial. This will probably generate some additional discussion, and if we don't get to it, I'm happy to come back if invited again.

John Halamka – Harvard Medical School – Chief Information Officer
But also in terms of timing, I think we can probably do our workgroup reports 15 minutes each at max, so you can go until noon, and if necessary, we'll squeeze a little time out of lunch because this is such an important discussion.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I want to start by echoing some of John's comments and referring back to HITSP and all the good work that has gone on before in terms of lessons learned and sort of the successes that HITSP has had. I think John has been very articulate about this in terms of describing some of those lessons. I've got a few them here.

Standards are not imposed. They are adopted, and if you want to get adoption, you have to solve real problems and not abstract ones, and you also have to engage the community for a sense of ownership. Standards should be harmonized and commissioned based on clearly articulated priorities, and to do that you need to have some way of deciding how to coordinate and how to prioritize the work that is going on and that adoption can be accelerated by the tools that can be provided. That includes things like vocabulary registries, easy to use sources for implementation guidance.

Implementation specification should be easy to use and, well, specific if we're going to be implementing them. We need to make sure that when we create implementation specifications we keep them as simple as possible, but no simpler. Try not to boil the ocean, but to solve real focus problems, and that perfection is the enemy of the good. As we think about wouldn't it be nice to do X, we need to make sure that we scope things and provide a framework that every time we iterate and we add something to it, it fits within a larger framework, and these kinds of lessons have happened with discussions that I've had with John about what are the good things that HITSP has done and how can we continue to leverage that work and make sure that we are moving to the next phase.

As we think about how to continue the work of HITSP, we need to begin thinking about how we can move towards more computational implementation specifications, ones that describe concretely and very specifically how things can be implemented. It provides some value in that we can scale our processes because we can build tools against things that are computational. If I have an XML description of something, I can build a tool against it as opposed to having a Word document that has links to standards and describes things explicitly.

We need to make sure from an operational perspective that we can link the use cases that are coming out of the HIT policy committee through standards from the inception of those use cases to the process of certification that we can test against them, and so we need to make sure that our certification processes, which is one of the things that we're charged to do within the office, are tightly linked to the standards and the implementation specifications. I think David spent some time talking about kind of how we do that with regard to the IFR and the standards and the relationship to the implementation specification.

We also have to make sure that we can develop the tools that support the compliance at the same time that we develop the standards. It does us no good to develop a standard to which we can't test if what we need to do is certify these things. As you take a look at the healthcare environments, we are blessed with a rich variety of SDOs that are producing all sorts of valuable things that help us with transport packages, vocabularies, value sets, security. An implementation guide really talks about all of those different standards that have been developed in many different organizations and brining them all together in a way that somebody can take a look at that and follow that to produce an artifact or a message or a piece of software that supports interoperability.

One of the things that we got is that with NHIN Direct we have a lot of community-driven sort of bottom-up approaches to developing solutions for specific problems. There's a series of use cases that the NHIN Direct project is going to work on, and all of those things are going to produce specifications and potentially test them in the software and give us guidance about how to proceed, but there are two different ways that you can sort of get interoperability or the way that you can do projects. One is it's command and control. You start at the top and say you shall do this, and we've certainly gotten some feedback that says we should just decide and go forward with that. The other way to do it is to sort of say we're going to let 1,000 flowers bloom, and we're going to have just a whole host of different things that are out there. It's really good for the customer, but it doesn't necessarily achieve the larger goal of interoperability.

So what we really want if you had your ideal is sort of this notion of focused collaboration where we can prioritize things. We have transparency in the process. We engage the community directly, and we try to iterate rapidly to get results. The idea here is that if we take the NHIN Direct project that is really focused on use cases and sort of bottom-up problem solving and put that within a framework that takes each of those iterations and builds incrementally the interoperability that we desire, perhaps we can get to that goal of focused collaboration, and I think that's one of the things that we're trying to explore and see if we can do.

Here's my interoperability framework, any questions? Let me just step through these things. Some of these are tied to recent statements of worth that have come out of our office, and I'd like to step through each of the different components here very quickly if we can just so people have a sense for what it is that we hope to achieve by coordinating the efforts of the standards and the use case development.

The first is that we know we have to do use case development to determine the functional requirements. HITSP has done a tremendously good job of sort of taking those things and aggregating together the existing standards into a focused implementation specification that can be used. For example, a use case might be a provider wants to send a referral to a specialist electronically. A use case should really describe what the services are, the functions that need to be performed, the standards, the package that needs to be exchanged, and then business rules and trust policies, all of the things necessary to actually provide a solution to that particular use case problem to be able to send that information.

One of the things that's important is that we need to engage a wide community in defining those use cases, and HITSP, again, is a mechanism that did that, and to focus on solving a real problem. That helps us with scope because it says here's the problem that we want to solve, and if there's something that would be interesting and useful but not necessarily helpful in solving that particular problem, it allows to sort of scope the work that we do. It gives us the ability to test so that if we've solved a problem we can say did our specification or did our solution solve the problem, and if it didn't, then maybe we don't have the right solution.

Focusing on use cases and things prevents analysis paralysis where you can sort of analyze yourself to death and you can kind of create way too much complexity. It prevents us from modeling in the abstract. By creating an open, transparent process, I think we can get to focusing on the real problems. NHIN Direct is an example of something that kind of follows these principles.

We also think that there's this notion of a use case steward. If you have somebody who has skin in the game who wants to solve a particular problem, if they have the ability to track this all the way through, we know that throughout each of the stages we might be able to have someone who really is making focus at harmonization is occurring, that the implementation specifications worked, that the reference implementations are the things that satisfy this. Then at the end of the day after you've done use case development and the functional requirements, what we want is a clear description that describes standards, services, and policies that solve that use case problem. Standard, services, and policies, you'll see that that comes up a lot in the way in which we define things.

The second part of all of this is that's a good process for solving problems, but if what we want is we want to leverage the ability of other people to solve similar problems and to have at the end of the day a cohesive and coherent set of standards, services, and policies, we need to make sure that those use cases that overlap leverage work that's been done in the past or that worked together. There's a need to be able to do harmonization, and so the kind of use cases that you might have is that e-Prescribing as a use case might overlap with adverse event reporting because we need to know something about how drugs are described, or we have to know about how people have allergies or reactions. Clinical care summaries might overlap with quality reporting because we'd like to leverage the work that's collected as part of clinical care and use that for quality reporting or laboratory data exchange and clinical decision support. We want to make sure that if clinical decision support needs to use information that comes in from a laboratory test result that there's consistency across those.

We need to make sure that as use cases come up and we're doing kind of an incremental focused way of doing this that we don't lose sight of the bigger picture to make sure all of these pieces work together. There needs to be sort of this harmonization task.

By having computational framework, XML or UML, it provides us the mechanism to provide some tools to do that, but we recognize that there needs to be strong governance and transparent processes as we do this and reach consensus around that harmonization. Eventually, what we really want is we want use case drive, sort of bottom-up development of problems and descriptions of those requirements in use cases with a top-down coordination that says, you know what, we have other information about e-Prescribing that might be useful for you as you think about how you might want to do adverse event reporting around drug interactions.

At the end of the day, if we have a use case that describes the standards, services, and policies for a particular use case, after harmonization, we should be able to describe those same standards, services, and policies now using sort of standardized ways of doing that. We have to standardize our standards if you will through a harmonization process.

One of the things that we've been looking at with regard to this is to try to figure out what are some best practices out there that have been used to do standards harmonization, and clearly, HITSP is one of those that has had a good ability to engage the user community and things like that, but we've also been looking at something called NIEM which is the National Information Exchange Model. They've developed processes within the federal space to be able to harmonize data exchange packages and come up with explicit representations that describe data elements, vocabularies, and value sets that support the exchange of information. There's been other work—and there's a typo on here. I apologize for that—within HL7 and within the NCI that takes a look at services harmonization and creating services-aware enterprise frameworks that describe services and the functional descriptions of what needs to be supported, conformance descriptions that talk about how do you test against those services, and governance descriptions about business rules and the like.

Finally, we need to have policy descriptions that are harmonized, and this is a challenge to be able to sort of take a look at policies and figure out a way to have consistency of how those things are described to solve a particular use case, but again, at the end of the day with harmonization, you want to have descriptions of the standards, the packages, the services, and policies, and there are different ways to do that. NIEM has processes to help. SAFE has processes to help, and we want to be able to leverage kind of those best practices and bring them together to help us with this.

I want to spend a little bit of time about the NIEM process. It stands for the National Information Exchange Model. It started as a Department of Justice initiative, but quite frankly, those processes have been generalized and have been supportive in lots of different agencies. For example, those processes supported the data integration and reporting for recovery.gov, and they found that by using the process, they were able to within eight months have over 100,000 exchanges with 200 different agencies and a whole variety of reporting to support the reporting of stimulus-related recovery monies into a dashboard. They were able to very quickly sort of get those data standards together in a consensus basis.

Currently, Health and Human Services are using the NIEM process to support child and family services, and it's been recommended by the Office of Management and Budget as a best practice. Not on in the federal space, but state and local governments are using similar processes and similar models to help support data exchange as well.

It basically has a common core of concepts that are explicitly defined and shared across different use cases. They use naming and modeling conventions that allow different groups to work independently, but then harmonize their work together, and for the geeks in the audience, it's based on the ISO 11179 metadata standard that's been used by NCI, NLM, and other standards organizations. It's underlying core is really consistent not only with national, but international standards for how data is described.

I call this the snake diagram. This is how they develop essentially the lifecycle, and it's difficult to read here, but I've called out some of the things that it does. We need to be able to develop use case models and have repositories for that and have the ability to have metadata and vocabulary services all integrated into this lifecycle. We have use case development, harmonization, and implementation specifications as being three things that we have within this framework that the NIEM processes will help us to support.

How does this work with some of the standards development organizations? I think it's important to note that this is not an attempt to create standards, but like HITSP is an effort to harmonize existing standards that are out there to support the use cases and the implementation specifications. Clearly, if we identify that there are gaps in standards for value sets, services, or data package descriptions, it's going to be critical for us to work closely with the standards development organizations to fill in those gaps.

If we need to sort of take something and say, listen, we've identified a use case for which there are no standards. We would like to work collaboratively with the standards organizations to help us develop those. We can develop implementation specifications, identify perhaps draft recommendations for the standards, and then work with the standards organizations to help fill in those gaps with this.

Again, one of the things that we've had some discussion about before is implementation specifications, and it's important that we get to the point where we can provide that to our customers so that they have explicit representations and specific descriptions of how these implementation specifications should be done. An implementation specification becomes sort of that description of standards, services, and policies that conform to the adopted standards and have sufficient details so that an organization can implement that. I don't want to go into all the different kinds of implementations, the ones that are platform-dependent and independent and things like that, but at a very high level if we think about the standards, services, and policies as the ingredients, the implementation specification is the recipe that someone would follow to be able to actually bake the cake or to create the software that would support that. Those things should be packaged together, and the interim final rule requires that we take a look at implementation specifications and provide those to the community in some fashion.

A reference implementation is really the cake. It's the thing that has taken those implementation specifications and created the software. We need to make sure that we create specifications that can be tested to make sure that we don't create a recipe that doesn't actually make the cake that we want, and so a reference implementation is a way of us testing to make sure that the specifications, we got them right.

In the diagrams I don't have any of the back arrows because it would get very confusing, but at every stage there needs to be feedback to make sure that if the reference implementation has a problem with it that we feed that back and that we update the implementation specifications. If the specifications have an existing problem with the standards, we feed that back through the process. Throughout this we make sure that we have those feedback loops and keep the process moving forward. A lot of people have looked at this and said, well, this looks very much like waterfall, but part of it is because I don't have all those loops in there because it just gets busy with the diagram.

If you think about an implementation specification as your test kitchen, your pilot demonstrations are actually getting it out there in the real world and having people examine. It's before lunch. I keep talking about recipes and cakes and things, but the pilot demonstration is what about high-altitude cooking and what about other kinds of things we didn't consider. We need to make sure that we get out there and we actually test these in real-world environments and, again, if there are problems with the reference implementation or with the specifications that we feed that back through the process as well.

The ONC needs to really serve in a role in which we can coordinate these pilot demonstrations. Again, with reference back to the NHIN Direct project, the idea that we can develop our implementation specifications, develop some software in reference implementation and test that in the real world, those are the kinds of roles that we think that the ONC can play in coordinating those activities and making sure that what we create for implementation specifications or what we recommend for standards actually solves the problems that we're trying to solve and does that in a way that we've tested in real-world environments. These are just recommendations that we had from the NHIN working group to do that.

Finally, certification and testing is sort of the culmination of those prior activities, and we've been working very closely with the NIST team and with Cita and her team to make sure that at the I guess left hand side of this particular diagram at the point that we're actually developing implementation specifications and we're harmonizing things that we don't create implementation specifications that we cannot test and that we engage NIST early so that we can make sure that as we're doing this that we can think ahead to what the certification and testing issues might be and make sure that we've addressed those as opposed to waiting until the very, very end and realizing that maybe we got something wrong and that we need to make some changes with that. Although this kind of looks waterfallish, the idea here is that throughout this we are going to have feedback at every step and make sure that we incrementally run this through. Incremental iterative approaches work when you've got an organizing principle that allows each of those iterations to fit into solving the larger problems that you're trying to do.

Finally, the goal here is to make sure that at some point we can make this much automated and self-serve, so we need to make sure that throughout this process that we provide tools and services that can help us browse through the existing set of standards that might be there. Make the implementation specifications available to people if they want to download them. Have the ability to look at a reference implementation to test your version against that version and to be able to make sure that there are conformance and schematrons and other things like that that helps us with the testing and certification of processes as well.

With that I'm going to stop. I'm sure that I've raised lots of questions with all of this, but the idea here is that if we can get to that sweet spot which allows for bottom-up innovation based on use cases and things like the NHIN Direct project, but do so in an iterative fashion that coordinates each of those iterations and provides a framework that we can integrate use cases with certification testing and make sure that each of those iterations can get harmonized around these implementation specifications. Maybe we can kind of push that ball a little bit further down the field and help us kind of achieve this goal that we have that was started with HITSP in trying to come up with these implementation specifications, and now we can move to sort of the next generation where we can start thinking about how we can do that harmonization and integration across all of those different specifications. With that I'm going to stop.

John Halamka – Harvard Medical School – Chief Information Officer
Well presented in record time. Just looking at your framework, I look at what AHIC was as being, that was the mechanism of generating our use cases initially, and we had the SDOs and we had HITSP, which was the harmonization of core concepts, and then where HITSP could have gone farther is to get the complete implementation guidance that would include code samples, reference implementations,

everything you need in one package, but for a variety of intellectual property licensing requirements, we weren't able to do that. We had a lot of indirection on the Web site. If you could take the lessons that we've learned and say, harmonization very important, SDOs very important, … requirements very important, but create a work product that a college student who doesn't know everything there is to know about 17 years of the history of informatics can say, here's the implementation specification, and there's this sample of XML and whatever, and there's a way to test it once I've actually implemented it. That would really help. I certainly applaud the way you've chunked this up. Let's start with Chris.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Thank you very much, and I want to repeat my compliments, Doug, from the vocabulary meeting of yesterday for an extremely thoughtful presentation and a cogent framework that you've presented. I'll spare you and the committee my rhetorical whining from yesterday and proceed to the questions, and there are two.

The first is a repeat, but I think it bears emphasis, and that is while the NIEM, which many of us has looked at fairly closely since it came out in the RFAs, is many things, few would accuse it of being a model, and the question of how, despite the name, of how we do cross-application, cross-use case harmonization in the absence of a model-driven framework clearly raises itself. The semantic specification is underspecified, but I think that's fixable. What seems less clear is how we address the cross-use case harmonization, and I don't think merely articulating that there is harmonization process is sufficient absent an overarching model, so that's the first question.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I don't know if I can give the same answer that I gave yesterday. It was probably a nonanswer. I recognize that in fact there isn't the equivalent of the RIM construct that helps with sort of integration across the various use cases. The fact that there isn't one doesn't mean that there couldn't be one, but you're absolutely right that there isn't sort of an existing sort of semantic model that exists within the NIEM processes right now. I don't have an answer except to acknowledge that and that as we go through this and as we work through this process that may be something that becomes important for us to include. We may find that we can get a long way down the road without that, but at some point we need to consider it. I think having people smarter than myself engaged in the process can help us sort those things out.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Let me move directly to my second question, and for me this underpins the classic tension between the strategic and the tactical. Your first presentation was purely tactical, and this is purely strategic. The obvious question is how are they interwoven because NHIN Direct isn't NIEM best I can tell, and yet we are as a nation potentially moving down that direction, and it begs how do we begin to adopt this kind of strategic framework within the context of tactical projects that are underway.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Well, I think part of what I hope to learn with the NHIN Direct project is to what degree can we use this bottom-up, use case-driven approach, and it's not inconsistent with the way in which the NIEM processes work. Much of the exchange that has been described or has been addressed with the NIEM processes are driven by real use cases and a real need to exchange information. That is part of that process. I don't think it's inconsistent with it.

I think it will be important for us as we move forward to make sure that we leverage what works, add to the NIEM framework things that are missing. We've already identified one which is this notion of the service descriptions that we think are going to be important with all of this as well. I think at the end, you probably saw in the previous slide, the NHIN Direct project. One of the things that we want to identify as an outcome of that project is what works and what doesn't within a larger interoperability framework that includes these kinds of tasks and the NIEM processes as well.

John Halamka – Harvard Medical School – Chief Information Officer
Let's see, we have Wes and Walter. Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
This is primarily just praise and support. I have over some time assembled a list of what I thought the challenges were that HITSP faced, and I just want to review them as a checklist. … This is a checklist. They have badly chosen use cases. They tended to focus on areas that weren't automated when we didn't know how to do standards … that were automated. Impossible deadlines. No feedback loop at all, I think opportunistically some came up, but it wasn't part of the process. Municipal intellectual property like oil and water, just the sources of the intellectual property were not amenable to being combined in a way that could create the simple kinds of targets that you're creating. That's it, so just asking you to comment on how you will deal with those issues.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
When it comes to use cases, I think our goal is to listen to the community in a similar way that we've done with NHIN Direct and try to solve sort of the simple problems and the ones that people care about. Clearly, there needs to be some sort of coordination among selection of use cases, and that would imply that there needs to be some sort of structure or coordinating function or participant that creates some way of prioritizing things. This could be kind of a governance feature. We've got people involved in the project, Brian Behlendorf who did a lot of work on Apache who's providing some guidance into how to manage open source communities and how we can create some of those priorities, but there's going to have to be some notion of how we choose use cases that's going to be driven by what people perceive as the important needs.

Impossible deadlines, unfortunately, we already have those, so I'm not sure I'd solve that problem per se. Even though the third was no feedback loops, I think this particular side I do have a couple of additional arrows and things like that, but I think without making a very, very busy slide, that is going to be absolutely critical for us to make sure that we have feedback throughout this process and that we don't throw things over the fence to the next group, and then when it doesn't work, decide that we need to reinvent it change it. That is fundamental that we need to have those sorts of feedback loops within this.

Intellectual property, I think that's an important comment, and I'm not sure that we have a solution for that just yet, but it clearly is one that we need to address as part of this. I don't have an answer for how to solve that except that if we can put in place a process that helps raise those issues and get some discussion about that, that's helpful as we try to sort through that issue.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Having worked that issue from the SDO side for 117 years now, you have the opportunity, you are in some senses in the United States their number one customer. You have the opportunity to demand changes inside the governance of SDOs that have been hard to accomplish just on a tradeoff between what's good for the SDO and what's good for the country, in particular, what keeps the SDOs budget going. If you are able to throw some development money at that, I think you will find the SDOs quite aware of the problem they have in looking for a way to solve it.

John Halamka – Harvard Medical School – Chief Information Officer

Good comment and just a quick comment on the use cases which is imagine that you created Pareto diagram that said, well, what are the actual transactions that all of us need to do to achieve meaningful use in 2011, 2013, and 2015, and then you say, well, then let's focus the early efforts on those transactions that are going to be done most frequently and, by the way, that there's some level of what we'll call standards harmonization readiness or standards maturity so that maybe it's the transaction everyone needs to do, but they're absolutely no standards that exist, so it's going to take awhile to do that. You take into account what's doable and what's necessary, and then I think that'll get us these nice bottom-up use cases.

I think what you said about the deadlines is right, the forcing function. The feedback you've actually put nicely in your diagram which is what HITSP did is it created these interoperability specifications which perfectly answered the use cases it was given and then handed them to the next party and said, here you go, and you created a more continuous process with these various RFPs that are interacting together and are coordinated. The intellectual property issues, yes, thorny question to be answered, but somehow SNOMED was licensed for the country. Maybe there are ways to license other standards that may be necessary for the country. David, did you have a comment?

David Blumenthal – Department of HHS – National Coordinator for Health IT
No, let's keep it going in order.

John Halamka – Harvard Medical School – Chief Information Officer
Okay, Stan. Sorry, Walter.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Just a couple comments, in reality, and I think John has pointed out, this diagram doesn't necessarily make a major departure from what was being done before in my mind. We're doing the same kind of processes. I have a couple of questions about the process itself. I think those are the ones that I personally saw within HITSP we had a lot of the challenges.

The first one was the development of the use case and the level of granularity and the whole process around use case-driven approach. We all remember some slides out there that depicted the first year use cases which were three. This is the next year which we seven. I hear there are 150 new ones that are coming down the pike, and every year we would handle as many as we could, and by we, I'm disclaiming that I used to be part of HITSP, of course. In my mind their concern was are we going to see truly an end? Is this an ongoing forever process, and what is the right approach of identifying and grouping and categorizing these use cases?

We use the process of population and consumer and provider perspective and those kinds of things, but in my mind one of the opportunities we have is to transition from there to a domain-driven use case approach in which domain experts around a particular group of messages and exchanges are gathered together to identify first of all the specific interoperability exchanges that need to be addressed with harmonized standards and then working them. To be more concrete, for example, we were thrown a laboratory use case and next was a medication management and next was a consumer access to health. Sort of the same group of people was running around from meeting to meeting, from group to group trying to participate and bringing some experts from the industry as well.

In my mind probably a way to drive that was take laboratories and say what are the messages that they are exchanging. Bring the laboratory industry along with the other partners together an develop the use case process and then the harmonization process, and then sort of the development is the ultimate product. Take the medication management or the whole pharmacy and medication management side and the specialties as well. That is I think an opportunity, and I believe actually other countries that have gone down this path have actually seen success around that, a domain-driven use case approach. That would be my first suggestion and a question for you.

The second one is really the maintenance loop. I think it's been mentioned sort of a feedback loop, but I think it's more of a maintenance question. We spent a lot of time obtaining these interoperability specifications, and we had in less than three years we had in some cases five or six different versions of each of these specifications. The question is about how do you see the maintenance process going there?

My third question which is more of a generic comment is perhaps the most significant challenge and I would personally say issue we had with HITSP was education. I'm here sitting as the former chair of the education committee of HITSP, and I can assure you that there were not enough resources, not enough time, and a confusion about who the audience is for this particular product.

Is the interoperability specifications document expected to be readable by my wife who doesn't work in healthcare at all, a physician who is a primary care provider 100% of the time, an information technology person within a facility, a vendor, a standards development group? Who is the audience for this implementation specification?

We acknowledge and recognize that there were many different audiences for the HITSP products, but we only had one product at the end which was the interoperability specification or the construct or the … whatever it was, but it was a very technical oriented document, and we never had the chance to develop the other products that could go along with the technical documents so that they could be directed to the appropriate audiences. Clearly, this technical document was not directed to the physician or the administrative person or my wife or someone like that or the public out there, but there are needs to develop such products aside from the technical ones. Those would be my three points.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I think that those are great suggestions. With regard to sort of a domain-driven approach, the maintenance loop I think is going to be a critical step, and we need to think about what are the tools and infrastructure and other things that would be supportive of that so that we can update and publish and examine and review and clean up the models as they get constructed.

I think you're absolutely right that education is important. I think if you look at the different activity that you can expect that one side you may want to engage the user community and the doctors and the providers and the people who are boots on the ground. On the other end, you're going to be perhaps talking to the vendors because you're talking about certification processes and things. In the middle you're talking about developers and technology folks. I think recognizing that there are different parts of this that will go to different audiences I think is a useful comment as well. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer
Stan.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Without explicitly stating, and I just want to verify, the implication is that this process would lead to things that, again, we might approve as standards for our next phase. I'm understanding that?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics

Yes, I think this is not an attempt to develop standards because we need to have ANSI-recognized, accredited bodies that are doing that, but clearly, we need to work arm-in-arm with the standards development organizations so that when we identify something, we can give them a heads up. One of the examples I think about is the end specifications for wireless transactions. You could for two or three years buy those with the draft specifications knowing that it still wasn't approved or gone through the entire process, so I think there are mechanisms where you can get things out. I think also the best standards are the ones that are out there, tested, and people are using rather than standards that we think are going to be useful and then we put them out there, and we realize that there might be challenges. That means that there's going to be this tension between having things out there that might be just before having an ANSI-recognized standard developed around that, but it's out there being tested and used and learning from that.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
My next two questions are sort of related, but what is the time scale for this? Is there any idea if whether we want to have some reference implementations a year from now or three months from now or two years from now? Can you give me any idea of sort of the timeframe for what you're hoping to accomplish certain milestones as part of this process?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I think the good news is that with HITSP and with the work that's gone on with FHA connect and with the implementation specifications that we already have around the NHIN gateway, there's a tremendous amount of work that's already been done that can help us jumpstart this process. In fact, we are working hard to make sure that those things are accessible and available early and leveraging what we've got already in this process. We don't need to start with a blank slate, start from scratch with use case development.

We've got a lot of use cases that we've already articulated. We've got a lot of specifications that are already out there. We've got a lot of standards that have already been identified. I think the challenge or the work is to get that into a consistent view, and that's work that I think we can do over time and move from where we are now which is to have a lot of specifications and a lot of things out there that are useful to the point where we've got them in a more integrated framework, and then we can begin to scale.

I don't anticipate, at least it's certainly not our goal to have to wait two years or three years before we get the first reference implementation. I think we've got a reference implementation that may with some work be within the FHA connect software. We just to make sure that we've got that and the implementation specifications in complete agreement so that we stay true to what we want to do with this framework to make sure that there's consistency across all the various boxes.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
My last comment, one of the keys there was harmonization across standards bodies, and I can imagine different levels of harmonization that could go on. In this particular case, I actually would probably argue for more rather than less, so one level of harmonization could be that we share logical models at some level, or we share use cases, that sort of thing.

It seems to me that we're at a juncture where in fact a much more fundamental sort of harmonization across standards groups would serve us well if we went actually back and said we have shared definitions for data types across NCPDP, HL7, X12, DICOM, IEEE, if we had a shared infrastructure for value sets, if we had computable, as you point out, computable models and those computable models were actually the same representation across those organizations that that would be fundamentally to our advantage so that we're not working on tooling and basically working from a different foundation in each one of those groups. The groups, in fact, I think the value added is in the knowledge and expertise they have in particular areas, and it shouldn't be controversial to define common mechanisms and a foundation set of data types and other things and in fact to support common frameworks and tooling that everybody could do their work, but now they're doing it in a way that in fact when I implement I don't have to worry about vertical … things and XML things and EDIFACT things and other things that just create diversity and don't add value.

The real value is in the content and in the structure. I guess this is more a comment than anything else. I hope that we take the time to do that fundamental level of harmonization across the standards organizations and that there's money and funding to do that. That's the sort of thing that really is strategic and would add value not just next year. Well, it might not add any value for 2 years, but it would then add value for the 5 and 10 and 20 years because we've done it that way.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I think that those are very, very good comments. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer
David.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes, David McCallie. First, just a comment or an observation and second a question. The observation is, and I think you've covered this pretty well, but just to say it in my own words, thinking it out loud maybe. The challenge will be to maintain the balance between how much of this is top-down and how much is bottom-up. When you put frameworks in place that get excessively top-down, you get detached from the real world, and they become kind of justifications of their own selves, but otherwise irrelevant. If you're too bottom-up, you get chaotic inconsistencies. The HL7 v2 might be taken as too much bottom-up, and v3 might be too much top-down in terms of the faults that we understand from both of those approaches, so getting that balance right will be the challenge. I think the grounding, the work in real-world implementations and real-world use would be the best remedy for the absence of imbalance. I'm glad to see that's part of the design.

That leads to my second question which is John at the beginning of the meeting made several comments that I think were to the effect that this process would mostly be back office, implying to me a certain passivity, that it follows rather than drives. You said some things that implied it's more of a driver of the process and not just kind of a documentation of what was achieved. Could you clarify or comment, and maybe, John, weight in with what you were thinking?

John Halamka – Harvard Medical School – Chief Information Officer
What I meant by back office is it's a set of organizing principles that helps ONC issue RRPs and coordinate the work. That's what I meant.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I think we'll need to serve some of those coordinating and organizing functions, but ultimately, the use cases that are identified should be driven by the community and the customers that we're trying to serve, the providers and the vendors who are trying to exchange information and ultimately the patients who will be benefitted by that exchange of information with the care that they receive.

John Halamka – Harvard Medical School – Chief Information Officer
Jamie, you had your card up?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, thanks, John. First of all, I apologize. I had to step out for awhile, so you may have already answered this, but I have a general question, and I'll ask it with a specific example. In the IFR it specifies content standards and transport standards and security standards, so when this process is used to develop implementation specifications for one area, whether it's content or transport, the general question is what's the relationship to the implementation specifications for the other related standards that work together with that? The specific example that I'll use is you've talked about using this process to develop implementation specifications for transport in NHIN Direct, so what then is the relationship of those transport specifications to the other implementation specifications for content, for the adopted standards, and how does that work?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Obviously, if we want to have fully specified implementation specification, we have the standards of services and sort of the policy framework in which they fit. The NHIN Direct project is going to focus on that transport question. Clearly, we have within the IFR specifications around content standards as well. One could argue that for some kinds of exchange in which there is even in the NPRM the exchange of information—and it can be structured or unstructured. It hasn't necessarily specified that—you could create an implementation specification that says here's the secure transport mechanism, and here's an unstructured package that can go with it that will solve a particular problem. It could be that another implementation specification says we're going to use the same transport, but we're going to have a structured way of what that package looks like.

Now, kind of going back to Stan's comment about the different levels at which you ca have harmonization and consistency, that would be an example in which you've harmonized at the service level or at the transport level, but you may not have harmonized at the content level because you've got something that's different there. I think having the flexibility to create, if the core concepts are all of your ingredients, to create as many different recipes as meets your use cases becomes valuable. You can them take those building blocks and assemble them to solve problems, and those solutions will be described in those implementation specifications.

The relationship, I think, and I'm not sure I've gotten your question exactly right, but is that we will have descriptions of content, and we will have descriptions of services, and we'll have descriptions of policies, but we hope to be able to have that in a framework that allows the reuse for different kinds of content, those contents, and the reuse of different kinds of services as needed to solve the use cases.

John Halamka – Harvard Medical School – Chief Information Officer
David.

David Blumenthal – Department of HHS – National Coordinator for Health IT
A comment or two. It's been a great discussion. Thank you, Doug, for persisting in this forum, but it's been very, I think, illuminating. There have been a number of pointy questions put to Doug about how are we going to do this and how are we going to do that and how are we going to do this and how are we going to do that.

I want to remind us all that you are what we are depending on to help us figure out how to do this. We cannot succeed unless you mobilize your knowledge to help us answer some of the questions you're asking us. Doug here is carrying the world on his shoulders, but he is really only trying to do the work that you all are advising him to do. If there is a better model for harmonizing across standards, please share it with us. If you have a better model than NIEM, or it shouldn't be called a model, whatever it's called. Please share it with us, the framework.

We are trying to do our best under difficult time constraints. We have the 2011 meaningful use now about eight months away. We have meaningful use NPRM for which standards or implementation specification and certification criteria are needed. It has to work. We're trying to keep open different options because we don't know, we're not clairvoyant. We don't know exactly what's going to work, and you all collectively are at the edge of this field. You were appointed because of your collective knowledge. I guess I'm asking for you to help us with these tough problems.

The other thing I wanted to clarify. It didn't come up here, but it's been circulating in the blogosphere, has to do with some speculation about whether NIEM is some kind of Trojan horse for government control over health information. That is because it is a government-developed mechanism for generating standards and implementation specification. Might it make it easier for health information to be transmitted, or might it make it inevitable that it is transmittable to the Department of Justice, the Department of Homeland Security, the CIA, the NSA. I don't know where else.

The answer to that question is absolutely no. I just want to say that for the record, absolutely no, and the Office of the National Coordinator would not participate in a standards development process that led to that. I say that because we want to take every opportunity to set the record straight on that and wanted to let everyone who's listening in on this know that that's the case.

John Halamka – Harvard Medical School – Chief Information Officer
Great, well, very well said. We are at lunch time, and here is what I'm going to recommend for our schedule. I think we can probably do our committee reports in 15 minutes each. If we could cut lunch to half an hour, try to come back about 12:45, 15 minutes each on the report, then we'll have time for the NPRM public comments, and then folks can get to their prearranged flights. Thanks very much, Doug, a very, very rich discussion. Thanks to all the other presenters this morning, very well done. We'll see you back at 12:45.

Welcome back from lunch, and we will now hear the presentations of our workgroups on the work in process and some next steps, and then importantly we'll hear about the certification NPRM. I'm sure that will also be a rich discussion. Steve Findlay, go ahead and tell us about the privacy and security workgroup.

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst
Great, thanks, John. I'm going to be able to take I think less than 15 minutes that you allotted to us. Dixie of course is sorry she can't be here. I think you announced at the beginning of the meeting she had a death in the family. Our group is going to focus over the next two, three months principally on one thing. That is consent management and the challenges there which I think we've talked about before so I don't need to wax on about that. The secondary thing is the review of the existing security policy inherent in the HIPAA security rule.

We're going to do this in two ways. Dixie is a member of course of the workgroup, the HIT policy committee's privacy and security workgroup, so we're going to work very closely with them principally through her, but others who liaison with the policy committee workgroup on that, with Deven and her crew, also with ONC. ONC has a new white paper that they just released. I got the email at 10:30 this morning on this issue, on consent management. That's going to inform our work. Other groups are working on this as well, and we're hoping to get some guidance from ONC, but Dixie will be coordinating all of that.

The second way we're going to work on consent management is through a series of educational sessions, and obviously, the policy committee is going to focus on the policy issues, and we're going to focus on the standards activities relevant to the work of this committee. Pursuant to that, we're going to launch four educational sessions April, May, and maybe flowing in some June (some details on the last slide) on activities around that.

Dixie created for the next two, three slides sort of an intro to this area. She would've taken a few more minutes than I will to describe all this. You have the slides. You can go through it. There are some definition issues here and some pretty slides and the next couple which we'll quickly go through, but this is basic information that she will talk about when we have these educational sessions which of course everyone, it's open to attend, including the public. These are some definitions of health information that we're all familiar with. The first two, of course, are really to HIPAA and the second one everyone knows about informed consent, so there'll be some attempt to reach some clarity around the categorization of these consent issues.

That's our world today. We all know it well. It works in a way, but in other ways it doesn't work so well. The world we want to go into is, a nice slide that Dixie pulled together, is digital. This is where we're headed, but we don't know how we're going to get there or what this is really going to look like.

HIPAA does require, as we all know, a signature, so that's going to have to be digital if that requirement is going to stay on the books which we all would assume it does. We're going to need to create a template and a sequence where we get permissions and capture them and have a digital signature and updates captured as part of the record, and permissions have to be interpretable by humans and computers, etc. You can look at the slide. I won't go through it too detailed, but suffice it to say that we've got to figure this stuff out, and it shouldn't be as complicated as all the stuff we're talking about this morning. This should be somewhat easier, but it's important.

Some more iteration and elaboration of the schema and the challenges, as you can see and also read on the slides for yourself. The sessions, the first one is on April 1 by a group called Oasis and then April 23 and then the others to follow thereafter, again, another one by Oasis. We hope to learn a lot over the next concentrated period, over the next six to eight weeks about this issue and, again, emphasis on coordinating with the policy committee and their workgroup. Next report to you from our workgroup will hopefully be more informed about the details of this and what we need to do here going into the next year. Thanks.

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… Web sessions?

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst
Yes, sorry, all Webinars.

John Halamka – Harvard Medical School – Chief Information Officer
As Steve has said, this all consents to the function of policy and technology which supports policy, and so this initial investigation is to really understand the baseline of what has been done to date with regard to any consent standards. Now, obviously as we've talked about multiple times in this committee, what has to happen is once we understand the policy requirements, we can understand then if these existent standards meet policy requirements or not.

Is there additional harmonization? Might other standards need to be commissioned? That will only be known once policy requirements are well understood. How granular should the consent be? What are the options, opt in, opt out, line item redaction? How should it all work? Steve said this multiple times that this will be a strict coordination between the HIT standards committee workgroup on privacy and security and the HIT policy committee workgroup on privacy and security. To open it up to your questions, any thoughts or concerns?

Okay, I think with a little glucose everybody has just gotten soporific. Well, thanks very much, Steve. Our next presentation from the workgroups, Janet and Floyd on the clinical quality workgroup.

Janet Corrigan – National Quality Forum – President & CEO

This is going to be a fairly quick update. Our workgroup has not met since the last meeting. We're are basically in a little bit of a holding pattern waiting for the policy committee to give us a bit more direction on 2013 and 2015 measures, but did want to share just a few thoughts.

First, the retooling efforts for the 2011 measures are well, well underway. Two major stewards that are doing the bulk of that work, the AMA, CCPI, and NCQA, and those measures with their new e-specifications will begin to roll into NQF starting around April. They're coming in in batches, but the work should be completed by early fall. I think one of the things that perhaps it's important to emphasize is that as a part of this work, this is a use case, and we will be identifying value sets that support more than one of these measures and appear to be useful value sets.

I wanted to just indicate I guess that if Doug is still here that there may be some opportunity to use this actually as a test case of sorts as you think about that earlier infrastructure that you had. If you want to try to build on the initial set of value sets that are going to be generated by product of this particular effort would be, or the specifications for these e-measures, certainly is a good use case. I think quality and clinical decision support is certainly one of the most difficult areas to satisfy, and very significant numbers of use cases will be generated there, so this might not be a bad way to begin.

Now, we did have a chance to communicate with the policy committee and emphasize to them that it's very important that we begin to get some clarity on what types of measures they're looking for for 2013 and 2015 because the timeline that is required to produce measures and to get them tested and ready to actually roll out as meaningful use is 18 months minimum if not closer to two years. As far as the measures that we selected for 2011, we definitely picked most of the low-hanging fruit in terms of available measures, so it's going to be a little bit heavier lifting going forward because we probably are going to be looking at measures that likely have to be developed.

Also, we have been giving some thought that there are more measures out there that might be particularly useful for 2013 and 2015. They probably reside within those well-developed systems that are well down the road in terms of HIT, and those measures typically haven't come forward to be considered for national standardized performance measures because they're in that limited number of sites that have really become wired. We're probably going to want to do a little bit of outreach to see if we can bring in other measures, whether it's from DHA, whether it's from the groups in Boston, yours, David, and certainly I've talked a little bit with Jamie at KP.

Another possibility, we have sites that have likely developed quite a few internal quality improvement measures, measures that could potentially be very useful and may well have given a lot of thought to measuring things that can only be measured when you have well-developed HIT systems. Ideally, those are the kinds of measures we want certainly for 2015, maybe even for 2013. We're starting to think creatively about how to build a pool of measures that can then be bumped up against those key concepts and the framework that the policy committee is likely to come forward, but we have asked them to move very, very expeditiously down that road.

That's really all we have to say. Floyd, did you want to say a few words about some of the standards issues related to the current measures?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Sure. We actually presented most of this the last time, so it's not much really to add to this. Basically, it was presented. The only one comment I would make is I responded to a question the last time that Wes had asked about is C32 enough information to manage quality measures. I would like to recant my answer that was yes and say it's not sufficient, but it's helpful because there is information not in C32 dealing with exceptions or exclusions to measures and even some of the inclusion criteria that are not there, but otherwise, there's not much else to say other than what's been said already.

Janet Corrigan – National Quality Forum – President & CEO
I think in some ways—

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Janet Corrigan – National Quality Forum – President & CEO
We'll clearly learn things in the process of retooling that have to be brought back to make sort of midcourse corrections, and I think that's really what's coming out of this as all these measures start to come in, and we hear from the stewards who realize certain things that perhaps are not 100% right.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Just a very quick request for clarification, Floyd, is that just the C32 per se, or is that true for CCD more generally?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
In answer to that question, CDA as the parent standard from which operations committee said CCD could be a floor CDA would represent almost all, but not entirely all of what's currently in measures as exclusions. CCD itself would not. There would be more missing.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
The C32 is a subset of CCD, right?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
C32 is less than the CCD, correct.

John Halamka – Harvard Medical School – Chief Information Officer
I think if you were to put this in a direct relationship, CCR has fewest data elements. C32 has more. Then CCD has more than that, and CDA of course is the full construct, but still, you think that there's something outside of CDA that would be needed?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Right. This was not discussed in the committee, but I do understand there is something called Pop CCR, population CCR, that is in development. We're investigating. I don't know any more about it.

John Halamka – Harvard Medical School – Chief Information Officer
Very good. Claudia.

Claudia Williams – Markle Foundation – Director for Health Policy

Thanks. I guess a question and maybe two questions. I know when we were looking at the NPRM and the IFR what was confusing is what was needed to pass forward summary results versus what was needed to within your walls calculate a quality result. To the extent you have a way to do that in your system, I guess my question would be why would you necessarily need to pass forward the exclusions as you report the results. That's the first question.

The second one is I really appreciated Doug's description of a iterative development process based on a real problem, and I think wonderfully you've laid out another opportunity to do this around the e-measures, and I'd love to hear a little bit about what the plans are for creating a similar kind of community for testing, what seems to be working and what doesn't. I think the original plan at least in the NPRM was to put out those e-measures in April, but I would love to hear more about what the plans are to actually have a community of people that are testing how that works and give you feedback and you allow for some refinement over time.

Janet Corrigan – National Quality Forum – President & CEO

Let me take a shot at that. When these e-specifications come in, they will actually start to get posted on the NQF Web site for public comment as they sort of come in in batches, and then we have an expert panel set up that's reviewing those comments and looking at them to make sure that they're okay. That's sort of the first quality control mechanism.

We think in terms of testing that there really are two things that need to happen, and to our knowledge there isn't a provision for either one of those to happen at this time. One would be to have a test bed set up of cases so that you could see whether or not if the information was entered in the right place in the electronic health record for a dummy set of patients. Do the specifications, actually, you get to the right calculation. That's something that we have brought to the attention of ONC, and we think … needs to be made for that to happen.

The second thing, though, that we're very worried about with e-specifications is that second error that would lead you to get incorrect results in terms of the performance results which is that you may well have a very well functioning EHR, and providers are not putting the information in the right place. Instead of using the drop-down menu for the problem list, they put it in a narrative portion somewhere, so you have to hunt to find it, and you're not going to be able to get the right results. There has actually been a little bit of work on that in a couple of sites. In Wisconsin there's been some interesting work, and they found that it's a very real problem. It really does have to do with how well you've trained your clinicians and how user-friendly the interfaces are for them to actually use. To our knowledge there isn't a requirement for that.

Now, some of these stewards that we're working with, PCPI in particular, they have put together a set of sites that they're using, and I wouldn't say they're random or that it's a stratified sample of sites at different levels, but rather more of a convenient sample, particularly a set of sites that they were able to get to participate in this, and they are actually rolling them out in those sites as a part of the testing. The timeframe of that is not clear to me as to how quickly that will happen. It certainly isn't going to happen at the time these specifications initially come in for comment, but I think these things will kind of be happening in parallel as we go forward.

I guess the third thing I would mention on the testing side that we've started to think about is that obviously you'd like to be able to test in most every site because you're going to find that providers are at different levels of acceptance and knowledge of how to use the EHR effectively, but one thing we haven't really looked at is there are those utilization measures that are also included in meaningful use. I really think it would be very helpful to take a look at the measures that are going to be used, trace them down to the particular data elements or capabilities in the EHR that support those, and see whether or not that collection of utilization measures cover the key data elements that are used to drive most of the measures. Then if you had a provider that did well and the 80% of patients had an entry in the problem list or 80% of patients had something about smoking/not smoking, whatever those are, if we've hit the right things in terms of the utilization measures, that would certainly be the first indication as to whether or not you're likely to be getting most of the cases reported in performance measures when they're calculated.

I think is personally an area where a lot of work needs to be done and not surprising by this committee wearing their other hat at NQF. Clearly, it's of critical relevance to our standards' setting process because we're focused on getting the reliable, valid results that are publicly reported using these measures, so it's really critical to get on top of all of the testing. A lot of that will get built into our standards' setting process over time. The issue here I think that's so critical is that's not going to happen on that same time schedule that's needed for these measures, so there need to be some special … as to how we're going to get some of that more sophisticated testing done.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Can I just add something to that and answer the first question which I know you asked as well? We actually have an expert panel now looking at those very same metrics that Janet referred to and identifying the items within the EHR, and we'll be coming out with a report sometime midyear of what the elements might be and a framework to be able to capture them and recommendations around that.

To answer your first question of if you're only doing summary reporting, why does it matter why you do locally, my understanding of certification expectations is you could locally be certified if you're sending from your EHR to another third party that is also certified to receive the information and then calculate. If you're working with that third party, you do need to interoperate and send the information to perform the calculation to do the summary report. There still has to be some interoperability between your local system and that system in order for that system to know how to calculate, so that was the reason for discussing methods for transmitting the data to be able to calculate.

John Halamka – Harvard Medical School – Chief Information Officer
It may be just useful to remind the committee of the Floyd taxonomy which says that an EHR has data. An EHR may—this is a may—transmit through an HIE to an aggregator of data which may have a reporting engine that could be inside or outside the aggregator and ultimately CMS or other entity is the receiver, so when you look at that, you could, if Dave McCallie decides that actually Cerner is going to be all five, the answer will be your Cerner millennium edition emits a numerator and denominator right to CMS when you're done or not, so hence the reason to define some of the standards along the way.

Janet Corrigan – National Quality Forum – President & CEO
I guess I would just clarify, though, that then it would depend on which model, but there would be a model in which it would be sufficient.

John Halamka – Harvard Medical School – Chief Information Officer
I would imagine, Floyd, if Cerner decided internally that it was going to be the HIE and the aggregator and the calculator and the reporter, and it was all done internal to the organization, then what would happen is it would emit a PQRI XML numerator and denominator, and actually, the data types that you've defined in CDA wouldn't, the types and the definitions are important, but the CDA wouldn't necessarily have to be used.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

That is correct, although I understand we don't determine certification requirements, but you're right.

John Halamka – Harvard Medical School – Chief Information Officer
I think what we all recognize is that in the concept of EHR certification and modular EHR certification there may be many configurations, and interoperability is between the borders of organizations. That's how our mission has essentially been defined, so sure, if in my case I am not doing the aggregation inside my four walls, I'm exporting them to a third party which is doing the computation and reporting, so yes, then I would use the standards as you've articulated, but others may not. Other questions? Jamie.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
No, Wes was first.

John Halamka – Harvard Medical School – Chief Information Officer
Okay.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Just to confirm an assumption, if we look at the meaningful use requirements in the NPRM, there are none of them in there that require data that crosses care delivery organizations. Is that right?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
It's a very difficult question to answer. I don't know that that's exactly correct because if there's a measure looking for a specific element that might have come from somewhere else, the data from another site would be acceptable including in the calculation, although you could say it could manually be entered into the EHR to be able to measure it, but some of the data would potentially have to come from outside the practice itself.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Just to try to clarify, by definition there's no data that is defined as having to come. There may be some data that is only available about the patient from outside the organization, but it's not like community readmissions in the future where you literally can't communicate that without knowing data from outside. In theory if I … saw this patient, I should be able to get all of the data I need for all of the 2011 requirements.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Let me give you one use case that might help to illustrate why I was hesitant on my answer. One needs to know if a condition was present prior to the occurrence of either an ambulatory encounter or a hospital encounter or I forget the other type of encounter within the first six months of the year in order to determine if in fact blood pressure management can be calculated that year. If the patient was not seen in my practice, but was seen and the diagnosis existed prior to the end of the first six months of the year somewhere else, then I could be held accountable for caring for that patient. It's a little more complicated than a yes/no answer. That was my reason for hesitating.

John Halamka – Harvard Medical School – Chief Information Officer
I think the spirit of 2011 stage one is to say we are not mandating a community repository of all records as a prerequisite for quality computation. It might exist in other institutions, and you could put such information in your EHR, but no one assumes that we're all going to have community aggregate repositories by 2011.

Janet Corrigan – National Quality Forum – President & CEO

In fact it was pretty explicit, I think, on the readmission discussion that in 2011 it's just readmission to your own facility, and then the thinking was 2013 would be readmission to at least, being able to look at least within two or three facilities perhaps, but then readmission community-wide. Your spirit is correct.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Just to restate what I think it states, there are areas where you may have to collect data the hard way, like having the physician ask the patient and document if they had a blood pressure diagnosis, or you may be able to collect it the easy way if you have interoperability with other places. Is that—

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
That's correct.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay, thanks.

John Halamka – Harvard Medical School – Chief Information Officer
Jamie.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I was just reflecting on the conversation about the different alternatives for performing the quality reporting and sending the measure data to CMS. My understanding is, I guess I'm looking for confirmation, Floyd, is that all the parts of that quality measure submission are defined as EHR technology, and so therefore, regardless of which of those models is used, whether it's done in a complete EHR or in modules that are split across different business entities, it would still have to be, maybe this is a placeholder for a conversation with Carol Bean later about the certification, but all those modules and those different business arrangements would still have to be certified, right?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
To my understanding, yes.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay.

John Halamka – Harvard Medical School – Chief Information Officer
Of course, the interesting question is if they are all internal to an organization or even internal to one system, then is the certification requirement for the use the standard between two pieces of one system really going to be standards' based, or might it be proprietary? You're right. This will depend upon how the certification is interpreted. Other questions?

Well, thanks, and we are now basically back on time. I realize I did not get approval of the minutes from the last meeting, the February 24 meeting. I don't know if folks had a chance to review the minutes, if there were any comments or questions. Okay, well, no objections or comments being heard. Judy, those minutes are approved. Let us go with Jamie.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. If I could have the first slide, I like actually being able to sit here and do it as opposed to going up to the head table. This is a nice pattern that we have here today. This is a report from the vocabulary taskforce of the clinical operations workgroup. We have held two public hearings, one yesterday, one last month, with an aim to develop recommendations around the governance of the use of the controlled vocabularies that's required for meaningful use for 2011, specifically around the subsets and value sets of those vocabularies. We're still digesting yesterday's seven hour meeting in this room which was very interesting, got a lot of input, but generally, what we heard I would say supports and extends what I'm going to present here which is a boiled down summary of what we heard from our first hearing last month.

One of the key questions that we asked all of our witnesses was what should the government's role be, and so what we heard very consistently was there needs to be a single central authority that has both legal authority and funding capability to govern processes around the creation, dissemination, education, maintenance, and so forth of both the defined value sets that are required for meaningful use, for quality measures, performance measures, and other purposes, as well as the convenience subsets that are the implementation starter kits, frequency-based subsets, and other perhaps clinical specialty-based subsets. We wanted to have a single point of coordination. Then yesterday we met with actually some of the different government agencies that have these responsibilities, and we had some discussion of different alternatives and some of the limits of that coordination for interdepartmental and interagency coordination.

We also heard that ongoing maintenance is essential. We heard that having a regular publication schedule that's known in advance is something that's very important for EHR implementers to know and understand in advance when they're going to get updates and maintenance and so forth. We've also heard that particularly the rural providers and safety net kinds of providers have particular difficulty in many cases with digesting and implementing updates, and so having a less frequent update schedule with essentially consolidated updates can be particularly important for safety net and rural providers.

We heard about the importance of binding value sets to the content exchange to context. We also heard very consistently a desire to remove licensing barriers, and there's a lot of support for the SNOMED model of licensing where the use of controlled vocabularies is required. We also heard very consistent with the implementation workgroup hearing feedback about making things easier for implementers.

I want to differentiate, also, between the value sets which are the defined code lists, for example, that are required for reporting the quality measures and calculating those measures where the value set defines the entire universe of terms and concepts that are used for a particular purpose versus these convenience subsets, and the convenience subsets are, for example, frequency-based subsets, the top 95% of routine lab tests ordered is a frequently used example of a convenience subset. We want to have mechanisms that are governed by the central authority that can make those convenience subsets available. Again, they're for the convenience of implementers, but those aren't essentially mandated requirements in any sense whereas many of the value sets will be essentially mandated when they're used particularly for performance and quality measures. We wanted to distinguish between those things, and there are other kinds of specialty subsets that may be created for particular medical specialties and so forth that in the view of the taskforce would have a lower priority than the general purpose subsets of the vocabularies that would be required to enable implementers to get going with their EHR implementation.

One other thing that we've heard that we also heard very consistently yesterday that didn't make it in to the slides was a recommendation to enable and facilitate alternative display names. Essentially, these are sort of clinician-friendly text that describes the codes. For example, I know in our institution we use, basically, we made up our own names for a lot of these codes, and that's what we use, and so I think that that frequently can help adoptions, so we wanted to promote and seek mechanisms for the sharing of these alternate display names. There may be different display names that are appropriate for different clinicians and different use cases and different settings.

Then let me just wrap up by saying some of our plans. For the clinical operations vocabulary taskforce, our basic plan is to refine the input that we heard from these hearings into recommendations that we'll come back to the full committee with next month, so about a month from now you should be hearing from us with a set of recommendations around governance. We also want to have a public meeting sometime between now and May to understand the framework of the ONC contract awards and how the framework that Doug went through with us and the entities that may be involved there can relate to the vocabulary work. We wanted to really understand that before we delve into our next major subject area which is really tooling and infrastructure options, alternatives, and making recommendations around tooling and infrastructure, which we intend to start that work in May with, again, public hearings starting on that in May.

One other item not related to this thread of activity that's just come up very recently is we also intend to have a public meeting probably within the next couple of months (I don't know if we can do it within the next month or not.) focused really on the need for the ICD crosswalks or ICD-9 and ICD-10 and operational considerations and to have that meeting jointly with CMS and ONC to explore and coordinate the meaningful use requirements for these crosswalks versus the other requirements that CMS in particular has for implementing these kinds of crosswalks.

Then in closing, not at the taskforce level, but at the level of the clinical operations workgroup, we also plan to have a meeting as soon as we can get it scheduled, which will also be a public meeting, to explore the claim attachments in relationship to meaningful use. I think many of you are aware that the recently passed bill that was signed into law requires claim attachments final rule to be issued by CMS. The NPRM included many different clinical document architecture attachments, and so the potential addition of the CCD as one of those CDAs on the list could make that highly relevant to achieving meaningful use possibly in 2011, but perhaps more likely in 2013. We're going to start to explore that possibility together.

John Halamka – Harvard Medical School – Chief Information Officer
Also, as you've said, who would've known that healthcare reform would have included a provision for finally getting the attachments completely standardized? This implies, of course, that we can now use administrative transmission mechanisms for clinical data exchange, so it gives us a whole lot of … transmission possibilities. Gina.

Gina Perez – Delaware Health Information Network – Executive Director
I just wondered if there'd been any discussion about LOINC codes or looking at subsets of LOINC codes and then standardization for orders and national compendia for example.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Previously, we did recommend out of the full committee I think that national order compendium was one of the priorities for publication. In terms of the vocabulary taskforce in general, we're focusing first on governance, rules of the road, sort of who should have what roles and what authorities and funding and how should particularly value sets, but also the subsets be governed and managed and disseminated and maintained for LOINC and everything else. Then we're moving into tooling and infrastructure. Then we'll get into the specific coordination issues on more of those specific priorities I think after that, so that's probably around the summer time in reality.

John Halamka – Harvard Medical School – Chief Information Officer
Certainly, my understanding is that with the work that Clem McDonald was doing at ALM, there are LOINC subsets that are nearing completion for 90+% of orderable lab tests, so it's all going to converge in the summer. That's the hope. David.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is David McCallie. My question, Jamie, is to pick up on that convenience subset discussion. I noticed you stressed the word convenience, and I'm curious to know that if you have a very difficult to use code set and you create a very convenient convenience subset and the vendors optimize user experience around the convenience subset, what happens if they need something that's not in the convenience subset, particularly with respect, Janet, to quality measures because the convenience subsets will be de facto the only ones people use.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
That's right, but you're going to have test orders or problems that are outside of those subsets. That's exactly right.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
It'd be nice if there was some coordination so that all of the codes and the retooling are in the convenience subset so that the odds of anybody—

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, I think that that's where certainly there's some overlap between the value sets and the subsets. I think that the value sets that are defined for the performance and quality measures, clearly we want to have all those as a minimum requirement for the popular convenience subsets, but there may be in fact a particular specialty subset that used for ophthalmology or dentistry that doesn't include everything for all the measures, so it's not necessarily that all of the value sets would be in all of the subsets.

John Halamka – Harvard Medical School – Chief Information Officer
Great. Other questions? Well, we've heard multiple times that the vocabulary subsets are so important and getting that governance right and figuring out who can change what and how it gets coordinated is really critical and then figuring out how to disseminate what infrastructure is necessary. Your plan sounds very reasonable. With that the last item on the agenda we have a report from Carol Bean and Steve Posnack on the certification NPRM. Hopefully, you've read it all, so this will just be …. Welcome.

Steven Posnack – ONC – Policy Analyst
Thanks for having us today. It's a privilege to be out of the office again. We didn't want you guys to be jealous of our presentation to the policy committee, so we came as well to present to you. For anybody that listened to the policy committee presentation, this is going to be the same show, so hopefully, we won't contradict ourselves, and we'll just march along forward. My name is Steve Posnack. I work in the Office of Policy and Planning at ONC. I'm here with Carol Bean. I, along with other responsibilities serve as ONC's lead for regulatory affairs which includes regulation development, and Carol works in—

Carol Bean – ONC – HHS
I work in the Office of Interoperability and Standards, and my primary responsibility at this point and for the foreseeable future is being lead on all of the certification and testing activities for ONC.

Steven Posnack – ONC – Policy Analyst
All right, and we'll just roll on through now. This is the slide I presented last, is it last week already? The days blend together. There are a lot of policy and a lot of planning going on.

From a conceptual standpoint, this is a slide that kind of conceptualizes what does it take to become a meaningful user. How does this all work? There's a policy architecture that's required to implement meaningful use which is comprised of there interdependent rule-making. Under each of the words, meaningful user of certified EHR technology, I've tried to indicate where those rule-makings fit in and how they relate to each other.

The first relating to meaningful users and CMS published a notice of proposed rulemaking, NPRM, on meaningful use which includes objectives and measure the potential meaningful users need to meet. Those objectives and measures are correlated to the interim final rule, which you have commented on which specifies the certification criteria and standards, and we also introduced the terminology that we were using correctly earlier about complete EHRs and EHR modules. Now, the one missing element that hadn't been in place until earlier this month that we published was a notice of proposed rulemaking on the certification programs which is a subsequent area of the statute that the National Coordinator was granted authority for, and we will go into more detail, which is why we're here today to describe the certification program.

We introduced two new acronyms for you to add into your nomenclature and your vocabularies, the first being ONC ATCB which stands for authorized testing and certification body, the second being ONC ACB which stands for ONC authorized certification body. These have particular roles depending whether or not they fall in the temporary certification program or the permanent certification program. The easiest way to remember that is the T in ATCB can also indicate which program it falls into.

These bodies, once they're authorized by the National Coordinator, will take the certification criteria that embody the standards that are adopted in the interim final rule and make sure that complete EHRs and EHR modules include the capabilities and the standards that are applicable to the criteria that they're being tested to. How does something meet the definition of certified EHR technology? Well, it needs to be certified through the certification criteria and standards by one of these authorized bodies, and that can either be a certified complete EHR which is something that does it all for the applicable setting that it's designed for, or it can be a combination of certified EHR modules, each of which are equivalent once they've been certified to all applicable certification criteria.

I'm going to move on. This is just the statutory authority that we're leveraging to reference and propose the rule for the certification program. It's important to note on the second one below that we have a consultative relationship with NIST in the first authority, and they also have specific responsibilities for the development of a conformance testing infrastructure which includes accreditation, and those are programmatic aspects that Carol will discuss in more detail.

These are just the policy committee recommendations that were both used to develop some of our proposals for the interim final rule as well as what we feel that we have embodied in this notice of proposed rulemaking related to certification, focusing certification on meaningful use, leveraging the certification process to make process on privacy and security and interoperability, expanding certification to include a wide range of software sources. We've tried to embody all of these kind of five core recommendations in our proposals.

Put simply, the programmatic purpose of our notice of proposed rulemaking is to establish the process for the National Coordinator's authorized organizations, so it goes through the application process, and what these bodies will need to demonstrate to the National Coordinator is that it's competent and it's capable and able to test and certify complete EHRs and EHR modules. It also includes some additional specificity on how complete EHRs and EHR modules would need to be tested and certified. This picks up on some of the issues that I don't want to say we left you hanging on in the interim final rule, but were best addressed in this proposal because of the scopes of each of the rules.

Moving forward, and I've tried to expedite my presentation a little bit from the last time to save some more time for questions. Rule making approach and this is really important that folks understand what we're doing here. From a context perspective, we looked at where do we want to be, what's our ideal state for certification.

Working backwards, we identified that we needed to have this interim step. We needed to have a transition period as the policy committee recommended, which is why we proposed two certification programs, a temporary certification program and a permanent certification program. The temporary certification program would be operational for certification essentially for meaningful use stage one, and we anticipate publishing a final rule for this certification program, the temporary certification program synchronously with the final rules for the interim final rule on standards and certification criteria which would be a double final rule so to speak and the final rule for meaningful use stage one. The permanent certification program would pick up where the temporary left off and begin certifying products for stage two.

Now, we proposed them both in one notice of proposed rulemaking because from a context perspective a lot of the core responsibilities and competencies that we expect them to demonstrate, these bodies, are the same, so instead of repeating them in two separate rule makings and giving you multiple rules to read and find on the federal registry Web site, we decided to propose them both in the same rule making and to finalize them in two separate phases. This has been done in other types of rules that the department has been engaged in.

We also understand the timing constraints that we're under, and we proposed a 30 day public comment period for the temporary certification program which ends April 9, so it is fast approaching, and I can just do one public service announcement that we're doing a Webinar tomorrow on the certification program's rule which will be more in depth and kind of be the navigation to the entire rule so to speak which will include a lot more detail than the presentation that's going on today. The usual suspects that see here will be putting that show on with our colleagues at NIST.

Then the permanent certification program proposals are open for 60 days. At the end of the 60-day comment period, all comments will be closed. Pretty much at 8:31, we will pack up shop on temporary certification program comments, go back into the Humphrey Building, and work as fast as we can at light speed basically the get this temporary certification program out and up and running so that we can accept applications and approve these bodies as fast as possible.

Very quickly at a very high level some of the commonalities and differences between the temporary and permanent certification programs, both include an open application process. Any organization that believes it's qualified and can meet the international standards for testing and certification that we've identified in the proposed rule are free to apply, and we've heard from numerous organizations about their interest. The temporary certification program includes a two-part application, the first being some provision of documentation, etc. that it follows international standards and then the second being a proficiency exam that we'll be working with our colleagues from NIST in order to verify that they're competent. These are some similar processes that an accreditation organization would perform, but in order to expedite the process and get the temporary program up and running, ONC, the National Coordinator, are taking on these responsibilities. That's different in the permanent certification program.

Organizations in both programs will be authorized to perform—and I have testing and certification in brackets because testing is only applicable to bodies under the temporary program—will be authorized to perform testing and certification of complete EHRs, EHR modules, or both. An organization could be authorized to just certify a specific EHR module that they want to meet a market need for, or someone could be authorized to certify a complete EHR and at the moment, as we've proposed, the plight of both inpatient and ambulatory EHRs.

The one difference that's kind of the centerpiece of the permanent certification program has to do with accreditation. In our proposals we described that the competencies for testing complete EHRs and EHR modules is different than certifying complete EHR and EHR modules. In order to demonstrate that bodies are competent to those, they will need to be accredited by different organizations to those competencies. The National Coordinator would approve an accreditation organization for certification competencies, and NIST, which this may be a new acronym for folks, through the NVLAP, which is the National Voluntary Laboratory Accreditation Program, would accredit the testing competencies.

Moving on, one aspect that I wanted to call out to folks' attention, this is more a column A, column B type of approach, so as I go through the summary here, just keep that in mind. We've proposed that the primary method, the capacity that an authorized testing and certification or authorized certification body, they must have the capacity to test and certify complete EHRs or EHR modules at their facility. A vendor of an EHR needs to be able to bring their product to the ATCB or ACB. That's column A at the moment. That's what we've proposed as a requirement. I think people can understand that as a very general requirement.

Secondary methods, we've proposed a number, which would be in column B, the ATCB or ACB would have to provide at least on of these other capacities for vendors or self-developers of complete EHRs or EHR modules. That would be at the site where the vendor has developed their product. It could be at the site where the module resides, so this could be the ATCB or ACB going physically to a hospital or some other healthcare provider or practice and actually testing and certifying their product … essentially.

Third would be remotely, we think that there a number of ways that this could develop over time, and we didn't want to preclude electronic means for expediting and making certification and testing more efficient. I'm going to turn it over to Carol. She's going to walk through our nifty graphics and explain a lot of the operational programmatic aspects.

Carol Bean – ONC – HHS
Hi. Some of this is going to seem repetitive, but it's going to be presented in a slightly different way. Repetition is good, especially when you have a lot of fairly complex moving parts, and so I'm going to try to reduce some of that complexity for you. I know I will not succeed in doing that entirely, but hopefully, we'll get a little bit closer.

I'm going to talk to four slides. The first two slides will focus on the proposed certification programs, temporary and permanent, with a focus on the primary organization and stakeholders. The second two slides will show how products and technologies are actually certified from a very high level in these two programs overlaid on the general process that's depicted in the first two slides, so I'm repeating within repetition.

I would like to remind you remind you that the basis of this design is essentially founded on three high-level principles. First, given to us by statute, is that we separate the development of the certification criteria and technical requirements from the certification process itself, and you have participated intimately in many aspects of that, but in particularly the development of criteria and the standard speaking to the technical requirements. A second basis for this design is to recommendations of the health IT policy committee, in particular the certification and adoption working group and extensive public input to that workgroup and to the committee itself.

Third, in consultation with NIST, here in addition to the aspect that they, we are all required to have NIST develop the testing infrastructure and to use that testing infrastructure. We worked very, very closely with them hand-in-hand developing the process itself to rely on their expertise and international standards and well-established best practices for conformance assessment that are widely used in many different industries. Just as an aside, I have learned innumerable new acronyms, some of which we're sharing with you, and I think I qualify now as an honorary NISTie having spent so much time with them.

As is true with any transition process, there are similarities and differences both with what you had before and what you are moving to. This temporary process has similarities to the previous program that has been in place for the last few years at least conceptually, and I would like to be very explicit that it also has many differences. It is not the same process. Some of the conceptual similarities are that, as Steve described, a single body would do testing and certification, but a couple of very important differences are that there will be multiple bodies to do that testing and certification instead of a single body that does all of that and, as mentioned before, a much, much greater role and responsibility for ONC in the entire process.

Another thing that I would like to tell you almost as an aside is we're not waiting until, while we cannot operationalize any of this until we are finished with the complete regulatory process, we are not waiting until then to plan and to develop artifacts and to develop contingencies and materials and all of that. We are working on many of the operational aspects right now. We have completed some of them. In various options we cannot finalize anything until the rule-making process is complete, so we're not doing that, but within the context of the various options that we have per rule and that would be consistent and responsive to public comment, we are doing that, so not to worry. We're not waiting until the rule is final before we sit down and start to plan. I think that has been a perception that some people have.

Moving quickly through this slide, it illustrates the importance and the role of NIST in developing the test method, but also tests methods themselves which deal with the protocols and the procedures, the data, and the tools that will be used for the testing process. These methods are already begun. They're developing them in waves. Some of them have already been published and are up on their public Web site right now for anybody to take a look at. We expect that this will generate a certain comfort level among both the vendors and potential testing and certification bodies, those who have developed things, so they can see the kinds of methodologies that will be used in the testing process itself.

The other things that I would like to draw your attention to here is that the Office of the National Coordinator will itself authorize, which is sort of like accreditation, the testing and certification bodies. There's not a line there, but NIST will participate in this process with us, again, part of their consultation rule for us, and we will in this thing, although we're not accrediting per say, we will use many of the international same standards that are used in an accreditation process to evaluate the competency and authorize the testing bodies.

This slide is of the permanent certification program or represents that, very similar in its key features, shows a couple of the differences. Here we are improving the robustification of the testing process and the certification process. We are fully implementing international standards, the ISO IEC standards. We will implement formal accreditation of both testing labs and the certification bodies, and there will be a formal separation between the testing and certification processes. Although it is possible that a single organization could do both, they would have to demonstrate very extensive and firm firewalls between those processes.

Moving now to the overlay here of the sort of the perspective of vendors or self-developers, those who have developed their own processes and the steps within the process from that perspective, as you can see, whoever would apply to the authorized testing and certification body with their technology, the module, whether it's a complete product or a technology, I am going to, because the next slide is over the same thing, the one, two, three, four, five are the same, it's overlaid on the permanent, it's a little busier, so your eyes will need a little bit more time to adjust to it. It's the same as far as what I'm talking about now. Essentially, somebody would submit whatever they need to be tested to the testing lab, get back a test report. If need be they would iterate on this process as much as they want until they pass or hit the level that they feel is appropriate. They would then be eligible to apply for certification to a certification body which would review and make a determination on their application. After that they'd receive certification.

Because we're going to have multiple certification bodies, we need to have a way to combine the information so that a potential purchaser does not have to go around and go looking all over the place, how many different certification bodies do I have to look at to find all of the certified products. What we are proposing is to get these reports on a regular basis from the certification bodies and compile them into a certified HIT product list, fondly known as the chapel, and this would be public-facing. It would a Web-based thing that, public-facing service, Web services thing that we have all kinds of fun plans for automating various aspects of it, but essentially, a potential purchaser could go there to see what are the products that are certified against what criteria, be able to determine whether their own, their self-testing once they've been certified, what's missing, how do I fill in whatever gaps that might exist. It also will be a resource for CMS should there be need to validate certification numbers and those kinds of things, but a resource for basically anybody because it will be a public-facing resource. The information at a minimum that would be provided to ONC is proposed in the NPRM, and this would include very specific information about the product and version number and the criteria to which it's been certified, etc.

I guess I would like to close. I hate to do this, but close with a couple of negatives, and that is what the certification program is not. We are not certifying integration of modules for modular certification. That is not within our scope at this point. Maybe it will be at some point in the future, but we're not doing that. We are not certifying individual installations on site other than the obvious exception where their full technology that they're using is self-developed, then we need to do this remotely, but we're not going to go certify what somebody has, if they've bought all these pieces, we're not going to certify that they can use them correctly, that they have installed them correctly, those kinds of things. We are obviously not going to certify anything having to do with meaningful use beyond the electronic health records system technology itself. That is CMS responsibility, but we are obviously working hand-in-glove with CMS to ensure that what we are doing fits with them and meets the needs that they have for their stuff. With that I will close.

John Halamka – Harvard Medical School – Chief Information Officer
Great, well, thanks very much. Just those last couple of points were so important, so if I as a small clinician buy standalone e-Prescribing, standalone lab ordering, outsourced quality measurements, and the cobbling together of all these modules, I feel, will get me to meaningful use, you are certifying each of those components, but it's really up to me to make sure that they actually work with each other which may mean my staff retypes from this to this. At the moment that's not in the scope of certification.

Carol Bean – ONC – HHS
That is not what we have proposed, and that is not what we have been mandated to do. What is the best way to say that?

Steven Posnack – ONC – Policy Analyst
At the present your description is accurate.

Carol Bean – ONC – HHS
I haven't quite gotten the ….

John Halamka – Harvard Medical School – Chief Information Officer
Well said.

Steven Posnack – ONC – Policy Analyst
I've practiced saying it in front of the mirror ….

John Halamka – Harvard Medical School – Chief Information Officer
That's followed by "Senator, I have no recollection of those events."

Carol Bean – ONC – HHS
But what we can do is help you determine which of those things when you want to go and buy the things that you yourself are going to cobble together, we can help you decide which ones are going to satisfy the full range of the certification criteria. That we do consider part of what we should provide.

John Halamka – Harvard Medical School – Chief Information Officer
Here's a complicated test case for you, and I promise this will be generally useful. Beth Israel Deaconess Medical Center self-develops almost all of its systems, but not all. That is, in some cases departmental systems are purchased, and in some cases we have outsourced third party services. If we as an organization want to achieve certification, I think what you've said is it it's a self-developed system, and let's say 80% of my EHR is self-developed, that goes through kind of a site certification for that component, but then if we happen to buy a product from Cerner, GE, Siemens, etc., which is itself certified, we would submit to the certifying body your site certification of the self-developed system plus the certifications that had been achieved through standard processes for commercial products.

Steven Posnack – ONC – Policy Analyst
Let me see if I can work around the answer to your question. If you have 80% of your systems that are self-developed, and you get that certified, you yourself take on responsibility to get that certified, and you buy a product that is also certified, in it's totality it meets the definition of certified EHR technology, you don't need to go back and get certified again.

John Halamka – Harvard Medical School – Chief Information Officer
Great, perfect.

Carol Bean – ONC – HHS
You can add them together.

Steven Posnack – ONC – Policy Analyst
We worked on the language in the interim final rule to describe this scenario multiple times. It got very tortuous towards the end. You don't need to go back and get double-certified is what I would say ….

John Halamka – Harvard Medical School – Chief Information Officer
That's a very important clarification because if those, especially academic health centers who mix and match and buy and build and integrate had to individually certify and collectively certify, that would be very challenging, so we certify our components either in the standard process, the vendor system, or through a site system, or through modular certification or whatever.

Carol Bean – ONC – HHS
Of course your organization takes the risk that they work well together, but as far as meeting the obligations of having certified EHR technology that you've accomplished that.

John Halamka – Harvard Medical School – Chief Information Officer
Right, and in an academic health center, we accept such risks. David.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
A naïve question from someone who doesn't know the space very well, but what's the rationale for separating the testing from the certification? Secondary question, I think I understand what the testing has to do. What does the certifying body have to do if the tests have been passed? Does it just read the paper?

Carol Bean – ONC – HHS
Well, yes, it reads the paper. To go to the second one first, it makes sure that it is from an accredited testing lab, that it has been tested according to appropriate and proper procedures, that the test … is fully accredited right now or at the time that the thing was done. A test lab, one of the easiest ways to think about it is a testing lab just gives a test. It tells you what your blood pressure is. It doesn't tell you whether it's good or bad. It just tells you here are the results. Here's what it is, and the certification body would then apply based on levels or criteria that we would give it, it must meet certain standards or certain levels.

There are also additional technical requirements that the certification body would apply. In addition to making sure that it's an appropriate test lab, they would agree to rules of proper conduct as they go forward with their stuff, any kind of reporting if they have problems, these kinds of things, and Steve can specify. There are a whole slew of these things, some of which we have proposed within the NPRM and some of which would be specified by the certification body themselves as they propose what they ask to propose for themselves to be authorized.

Steven Posnack – ONC – Policy Analyst
The way I try to keep it straight for myself is with hopefully a simple example. It's kind of the difference between quantitative versus qualitative analyses. On testing side if we were to say we wanted to make sure that we could certify toys as being lead-free, you would submit a toy off the assembly line to a testing body and say tell me how much lead is in this, and they'd come back with a result that says 20 parts/million. That's all you get. You get a quantitative result. Then you would bring the toy and your quality manual and your design processes and how your factory is set up and if you've got particular filters, etc. to keep lead-based particulars from getting in your paint, and you bring it to the certifying body, and they would inspect some of those qualitative factors in addition to your test result. If the standard for lead-free is 10 parts/million, then you fail that in addition to the other qualitative factors that you'd review.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
That's a great example. That makes a lot of sense. Thanks.

John Halamka – Harvard Medical School – Chief Information Officer
Kevin.

Kevin Hutchinson – Prematics, Inc. – CEO
I'll use an example that is simpler for my brain, cars. I love cars. You go to an inspection facility, right? It's been certified as an organization who can inspect the cars, but a lot of the testing equipment that's there to test your emissions and other things would actually be kind of the test lab if you will. In that case it's a piece of equipment, but it could definitely be equipment and human, right? The question I have, though, around that is, is it the expectation that these bodies, the certification body and the testing laboratories be self-sustaining from a business model standpoint, or is this something that's going to be government-funded? Going back to my car example where there's an inspection and the consumer pays a fee for that inspection, but there may also be some state fees coming in for being an inspection site. Is it a combination, or are we going back to someone needs to also prove that they can have a sustainable business model, be a sustainable entity to be a certification body or a lab?

Carol Bean – ONC – HHS
Yes.

Kevin Hutchinson – Prematics, Inc. – CEO
Presently as stated is accurate, right?

Carol Bean – ONC – HHS
Those are some of the additional aspects of what would be required in the certification process that they the vendor, now, let's don't confuse the vendor or the developer from the certification body. Our proposal is around the process itself, but what they are checking is whether a certification body will check, the accreditation process would make sure that the test lab is accredited. The certification process would check that what they have done is good.

They would also make sure that the vendor has the quality measures and the quality manual kind of stuff, as Steve said. Some of that is, is it a fly-by-night thing? Are they sustainable? Do they have the personnel? Do they have those kinds of things?

Again, it's not subjective, but it is perhaps a little more qualitative in addition to the quantitative side of things. We believe that there's a business model for this, and we have developed this, and it's one of the reasons for encouraging multiple and in essence … requiring multiple bodies as we can is because we believe that there is a business model, that the prices will be driven down as competition enters that market. We would like to encourage a market for these services.

Certainly, in the temporary program, some aspects of that, if you look at some of the things, we have far fewer boxes because the government proposes to take on more of the roles that eventually would be done in the private sector. While there right now is not a healthy market business for those kinds of things, we expect that to develop, and all signs that we've received indicate that that is the case. We've heard from multiple organizations that want to serve in all of these capacities, not each, but multiple organizations for each of the capacities. Personally, I'm relieved and gratified, but again, in many of the other industries that do this, there's ample evidence that there is a very solid business model for this.

Steven Posnack – ONC – Policy Analyst
I think Carol said it all. The challenge with any regulatory process is how do you tabulize the market and provide some flexibility while not stifling innovation and making it inflexible in other areas. In our proposals, as Carol mentioned, we hope to provide an environment where it's fruitful for a number of organizations to become certifying bodies. Clearly, there are enough market for forces out there to make it worth their while, and certification is going to be an ongoing process.

John Halamka – Harvard Medical School – Chief Information Officer
We assume that these labs and the certification bodies would compete on price, and so if one says $28,000 and the other says $500, the market may decide that $500 sounds better.

Kevin Hutchinson – Prematics, Inc. – CEO
Because you would make the assumption that quality is going to be same across all of them.

John Halamka – Harvard Medical School – Chief Information Officer
There's going to be some variation—

Steven Posnack – ONC – Policy Analyst
… floor presumably that you'd set in your approval process.

Carol Bean – ONC – HHS
In the approval process and thanks for the opportunity, I think they will compete, and I think the prices will rapidly go down. Somebody asked about a race to the bottom, and I think they were asking about the quality of the testing and certification, but I think the race to the bottom will be on price because we set the technical requirements, and those are not set by other groups. That actually comes back to the

question we didn't answer. One of the reasons for doing that is we were told to, but the other reason is it's the right thing. It's the fox in the henhouse kind of thing.

Kevin Hutchinson – Prematics, Inc. – CEO
Although, I do know where you can get a car inspected in five minutes versus 30 minutes, but I'll keep that to myself. If anybody wants the address to that, just let me know.

Steven Posnack – ONC – Policy Analyst
Just to follow really quickly on Carol's point about the baseline level, accreditation will really help provide the commonality of the testing and certification just like with academic standards, etc. One accredited school hopefully is producing the same people as another accredited school. That may be tortured analogy for some folks in the academic institutions, but similar principles apply at least.

Carol Bean – ONC – HHS
If I may just have one final say on that aspect of it, we're not pushing the boat out and walking away. We, ONC, and through this committee and through our other advisory committee are maintaining involvement in all of it. We're not just throwing it out and letting it go, so we will ensure that the quality stays high.

John Halamka – Harvard Medical School – Chief Information Officer
Great. Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Full disclosure, I'm on the board of CCHIT. I fully support the notion of having multiple testing organizations, multiple certification organizations. I do not believe that separating the organizations reduces the incentive on the testing organization to be the one that is easier to get tested by just like this format here. The fact is that if the vendor picks the testing organization, that's how it matters. We know from CCHIT that if a vendor spent $30,000 to get certified they spend $70,000 getting ready to get certified. The actual cost of the certification is the minority of the total cost.

Now, there is a provision in the regulation that says that the primary means of testing will be at the software lab's facility. If I understand that, that means that everyone who successfully applies will have such a facility. They may also support secondary testing. Is that right?

Steven Posnack – ONC – Policy Analyst
It would be at the business.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
In other words CCHIT, which has tested 100 EHR more or less, multiple versions many times, has a paid set of examiners. They have integrator reliability that's been established. They have to go to the extra expense of setting up a lab because they have never done it at their place. They have only done it by the means that you say are secondary and therefore not sufficient to qualify. Is that correct?

Steven Posnack – ONC – Policy Analyst
It's a proposal, so I would encourage public comment on that.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I would encourage anyone in the public who's worried that the way it is proposed it may be leading towards acceptance only of very high-overhead testing labs to consider that point.

Steven Posnack – ONC – Policy Analyst
That's a fair point that we can take into consideration.

John Halamka – Harvard Medical School – Chief Information Officer

Very good. Any other comments? Well, thank you very much for that presentation. It was very clear. Your graphics were great. No problem. Judy, I know we have time now for public comment, so let's open it up.

Judy Sparrow – Office of the National Coordinator – Executive Director
This is the public comment portion of the meeting. We have a gentleman in the room. Please identify yourself, name, organization. You have three minutes.

<Q>: My name is Tom Morrison. I'm a Chief Strategy Officer at NaviNet, and also, I'm community chair on some of the clinical … collaborative activities. I wanted to just comment briefly on one of the concerns that were raised about NHIN Direct by Marc around usability and just describe a bit of the experience that we've had in the marketplace.

NaviNet is a provider network that effectively has established a transport layer to about 850,000 across the country in the administrative side of healthcare. In a model very, very similar to NHIN Direct where the transport layer is common, there's a base workflow that establishes a place for these content packages and process packages to plug in, and what we've found has been great acceptance in the provider community. We're doing literally hundreds of millions of transactions a year in that exact model, and so I think while some people have had difficulty with that model, there have been questions about usability. Our experience has been that if you focus on workflow and workflow triggers to enable the delivery of these packages, it opens up a whole world of possibilities and really does start to facilitate the kind of innovation that we're all looking for. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Tom.

John Halamka – Harvard Medical School – Chief Information Officer
Thanks very much for the comment.

Judy Sparrow – Office of the National Coordinator – Executive Director
Nobody else in the room. Nobody on the phone. Turn it back to Dr. Halamka.

John Halamka – Harvard Medical School – Chief Information Officer
Just want to make sure no one else on the phone for comment. Great.

Operator
Yes, we do have Robin Raiford just queue up for comment. Please proceed with your comment.

<Q>: Hi, it's Robin Raiford, and I just wanted to give a shout out to some people I'm not sure have been publicly thanked, and it is obviously the HIT standards committee, tremendous amount of work and the policy committee, a lot of work, but if you're attending this remotely, the most important person in the room is that guy at the soundboard turning those microphones on and off, so I'd ask the audience to give that guy a round of applause because that lets you attend this remotely. I just want to also publicly thank, Judy, I'm not sure who on the team at the ONC updates the Web site, but all the massive amounts of information and the continual updating of the Web site. They do a great job so that you don't get lost in the Web site and you can find the new stuff …. I just wanted to get that on the public record and say thanks.

John Halamka – Harvard Medical School – Chief Information Officer
Wonderful. Very welcome comments.

M
Robin.

John Halamka – Harvard Medical School – Chief Information Officer

Are you there?

<Q>: Yes, I am.

M
You're falling behind on indexing regulations and laws. When do we get your next—

<Q>: … when it came out a second time, then it's got to be reindexed again. I'll check that out.

John Halamka – Harvard Medical School – Chief Information Officer
Well, yes, it's the staff behind the scenes that makes all this possible. Thanks to everybody at ONC. Thanks to the technical staff and look forward to getting together again in April. There's a lot of work going on, a great meeting today, a lot to digest, and I will summarize it all on my blog. Should be live about 9:00 tonight. With that the meeting is adjourned. I will see you in April.

Public Comments Received During the Meeting

1. Is there any plan for the HITSP to standardize communication of evidence based order sets?

2. What consumer centered design testing will be included in the testing process of EHR's?

3. A password protected encrypted document can be emailed. That can still be considered secure, as long as the password that unecrypts the file is not sent out in the same email.

4. What is NHIN Directs mechanism to give feedback to the specifications feedback to the originating organization?

5. John H, my question is: What will be the feedback mechanism to correct the specifications? e.g. and who will be the ones to redo the specifications

6. How are private industry partners commenting on the open source software to make changes as it progresses?

7. What is Wes's blog address?

8. Is the World Wide Web Consortium involved in this interoperability attempt? They need to reduce their number of XML schema standards and provide interoperability of the XML schemas with HTML (XHTML)

9. If we integrate multiple 3rd party technologies into our EHR and only 20% of the technologies are not certified products, do we need a site certification?

10. Abbreviations are being overused. The average listener cannot be expected to know their meaning.

11. The development of a major software standard was done by the Department of Defense with the Ada programming language. Have you looked at their experience?

12. How do you plan to monitor the safety of the software? Are you going to perform quality assessments?

13. NIH SBIRs do not cover standards development because the product does not provide a direct path to a profitable business. Are you coordinating with NIH, particularly their Grants Administration?